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TRANSMITTAL OF APPEAL BRIEF (Large Entity)

Docket No.
DI-5717 US

In Re Application Of: **Watkins et al.**

Serial No.	Filing Date	Examiner	Group Art Unit
09/871,863	**June 1, 2001**	**K. Menon**	**1726**

Invention: **HEMODIALYZER HEADERS**

TO THE COMMISSIONER FOR PATENTS:

Transmitted herewith in triplicate is the Appeal Brief in this application, with respect to the Notice of Appeal filed on

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Dated: **January 26, 2004**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant(s): Watkins et al.
Appl. No.: 09/871,863
Conf. No.: 1448
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Title: HEMODIALYZER HEADERS
Art Unit: 1723
Examiner: K. Menon
Docket No.: DI-5717 US

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' APPEAL BRIEF

Dear Sir:

This Appeal Brief is submitted in support of the Notice of Appeal submitted by Appellants on November 25, 2003 in the above-identified patent application. This Appeal is taken from the Final Rejection dated June 26, 2003.

I. REAL PARTY IN INTEREST

The real party in interest for the above-identified patent application on Appeal is Baxter International Inc. by virtue of an Assignment recorded at the United States Patent and Trademark Office.

II. RELATED APPEALS AND INTERFERENCES

Appellants do not believe there are any known appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision with respect to the above-identified Appeal.

III. STATUS OF THE CLAIMS

Claims 1 and 3-28 are pending in this application. A copy of appealed Claims 1 and 3-28 is attached in the appendix. In the Final Office dated June 26, 2003, claims 1 and 3-28 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over DE 3435883 A1. A copy of the Final Office Action is appended hereto as Exhibit A of the Supplemental Appendix and a copy of the cited reference is appended hereto as Exhibit B of the Supplemental Appendix.

IV. STATUS OF THE AMENDMENTS

No Amendments After Final were filed.

V. SUMMARY OF THE INVENTION

The present invention relates generally to methods of providing therapies. More specifically, the present invention relates to methods and devices for providing dialysis. (Specification, p. 1, lines 6-8.)

Due to diseases, insult or other causes, the renal system can fail. In renal failure of any cause, there are several physiological derangements. The balance of water, minerals (Na, K, Cl, Ca, P, Mg, SO_4) and the excretion of daily metabolic load of fixed hydrogen ions is no longer possible in renal failure. During renal failure, toxic end products of nitrogen metabolism (urea, creatinine, uric acid, and others) can accumulate in blood and tissues. (Specification, p.1., lines 9-14.)

Dialysis processes have been devised for the separation of elements in a solution by diffusion across a semi-permeable membrane (diffusive solute transport) down a concentration gradient. Principally, dialysis comprises two methods: hemodialysis; and peritoneal dialysis. (Specification, p. 1, lines 15-18.)

Hemodialysis treatment utilizes the patient's blood to remove waste, toxins, and excess water from the patient. The patient is connected to a hemodialysis machine and the patient's blood is pumped through the machine. Catheters are inserted into the patient's veins and arteries to connect the blood flow to and from the hemodialysis machine. Waste, toxins, and excess water are removed from the patient's blood and the blood is infused back into the patient.

Hemodialysis treatments last several hours and are generally performed in a treatment center about three to four times per week. (Specification, p. 1, lines 19-25.)

Hemodialysis typically involves the use of a dialyzer. Dialyzers generally comprise a housing or casing. Located within the interior of the casing is a fiber bundle. Typically the fiber bundle is comprised of a number of membranes that are oriented parallel to each other. The membranes are designed to allow blood to flow therethrough with dialysate flowing on the outside of the membranes. Due to an osmotic gradient that is created, waste products are removed from the blood through the membranes into the dialysate. (Specification, p.1, lines 26-32.)

Accordingly, dialyzers typically include a blood inlet and a blood outlet. The blood inlet is designed to cause blood to enter the fiber membranes and flow therethrough. Dialysate is designed to flow through an inlet of the dialyzer and out of the dialyzer through an outlet. The dialysate is designed to flow across the outside or exterior walls of the membranes. (Specification, p. 2, lines 1-5.)

One of the issues with prior dialyzers is that the flow of the blood through the fiber bundles may not be entirely satisfactory. In this regard, blood may not flow sufficiently through the entire fiber bundle. Rather, there often occurs clotting in areas of low or no flow. For a cylindrical dialyzer, these areas are usually found along the outer perimeter of the surface in which the fibers are embedded. (Specification, p. 2, lines 6-10.)

The present invention relates generally to dialyzers for use in dialysis therapies. More specifically, the present invention relates to dialyzers having an improved header design providing an improved flow of blood into the interior of the dialyzer and specifically to the fiber bundle. This eliminates, or at least substantially reduces, the zones of low flow thereby reducing the potential for clotting while improving the ability to rinse the header of blood. (Specification, p. 2, lines 15-20.)

To this end, the present invention provides a dialyzer inlet header comprising a body that defines, at least in part, an end of the dialyzer. The inlet header includes an inlet channel providing fluid communication from an exterior of the dialyzer to an interior of the dialyzer, the

inlet channel defining a fluid flow path that is axial to a fiber bundle located in the interior of the dialyzer. The dialyzer also includes at least one member for modifying the fluid flow path of a fluid as it exits the inlet channel. The member for modifying the fluid flow path includes a curved vane extending from a portion of the body of the inlet header. For example, the dialyzer inlet header can include eight vanes. (Specification, p. 2, lines 21-24.)

The inlet channel can be located at a center of the inlet header body, and where the inlet header can be sealed to an end of a dialyzer casing. The member for modifying the fluid flow path can also includes a curved channel extending into a portion of the inlet header body, where, for example, the dialyzer inlet header includes eight channels extending into the body such that the member obstructs the flow of fluid as it exits the inlet fluid channel. (Specification, p. 2, line 30 to p. 3, line 6.)

The member can include a disk located under an exit opening of the inlet fluid channel, where for example the inlet header body includes a plurality of curved vanes and further, the body can include a plurality of curved channels. (Specification, p. 3, lines 7-10.)

The present invention provides a dialyzer. The dialyzer includes a body defining an interior and having a first end and a second end, and a fiber bundle located in the interior. A blood inlet is located at the first end of the dialyzer and includes a fluid flow channel that causes the blood to flow in an axial direction with respect to the fiber bundle. A member is located in juxtaposition to the blood inlet that causes blood to flow to a perimeter region of a first end of the fiber bundle as it enters the dialyzer. (Specification, p. 3, lines 11-17.)

The member for modifying the fluid flow path is a curved vane extending from a portion of the inlet header body. This can define a curved channel extending into a portion of the inlet header body. For example, the member for modifying is a disk located under an exit opening of the inlet fluid channel. (Specification, p. 3, lines 18-23.)

A dialyzer header is also provided that includes a body member having an inlet channel providing fluid communication from an exterior to an interior of the header. The inlet channel defining a fluid path that is axial to a body of a dialyzer to which the dialyzer head is attached and the body member including a plurality of members that impart a circular motion to the fluid as it enters the interior of the header. (Specification, p. 3, lines 24-29.)

The members can include a plurality of curved vanes, or for example, the members are a plurality of curved channels. In this regard, the member can obstruct the flow of fluid from the inlet channel as it enters the interior of the header where, for example, the member that obstructs is a disk located under the inlet channel. (Specification, p. 3, line 30 to p. 4, line 3.)

The present invention provides improved dialyzers for providing dialysis to a patient. Although the present invention is designed for use in hemodialysis, the present invention can be used in other and non-traditional therapies. Such methods include, for example, continuous flow or regeneration therapies which may or may not include hemodialysis, for example, continuous flow peritoneal dialysis. Further, although the present invention is designed to be utilized for hemodialysis in patients having chronic kidney disease or failure and therefore require regular treatments, the present invention can be utilized for acute dialysis therapy, for example, in an emergency room setting. (Specification, p. 5, lines 11-19.)

A further discussion of the present invention is provided below and illustrative thereof with references made to Figures 1-4, a copy of which are provided on a single sheet in Exhibit C. Referring now to Figure 1, a dialyzer 10 is generally illustrated. The dialyzer 10 includes a body member 12 that generally includes a casing. The casing includes a core 14 section as well as two bell members 16 and 18 located at each end of the dialyzer 10. Located within the core or casing is a fiber bundle 20. (Specification, p. 5, lines 20-23.)

Located at a first end 21 of the dialyzer 10 is a fluid inlet 22 and at a second end 23 a fluid outlet 24. The fluid inlet 22 and fluid outlet 24 are defined by a fluid inlet header 26 and a fluid outlet header 28, respectively. Generally, the fluid inlet header 26 is designed to allow blood, or other fluid, to flow into an interior of the dialyzer 10 through the fiber bundle 20. The fluid outlet 24 is designed to allow the dialyzed blood, or other fluid, to flow out of the dialyzer 10. As illustrated, blood flows into the dialyzer in an axial direction "A." As used herein, axial means that the blood flow into the dialyzer 10, and specifically the inlet channel 27 of the inlet header 26, is in the same direction as the flow of blood through the fiber bundles 20. (Specification, p. 6, lines 4-12.)

As further illustrated, the dialyzer body 10 includes a dialysate inlet 30 and a dialysate outlet 32. In the embodiment illustrated, the dialysate inlet 30 and dialysate outlet 32 define fluid

flow channels that are in a radial direction, i.e., perpendicular to the fluid flow path of the blood through the fiber bundle 20. The dialysate inlet 30 and dialysate outlet 32 are designed to allow dialysate to flow into the interior of the dialyzer 10 bathing the exterior surface of the fibers in the fiber bundle 20 and then out through the outlet 32. As is known in the art, this causes waste and other toxins to be removed from the blood through the semipermeable membrane of the fibers and carried away by the dialysate. (Specification, p. 6, lines 13-21.)

If desired, the dialyzer 10 can be one integral piece. In this regard, the inlet header 26 and outlet header 28 can be integrally molded to the remaining portions of the dialyzer body 12. However, in a preferred embodiment, the dialyzer headers 26 and 28 are sealed to the first and second end of the dialyzer body 10. This allows the fiber bundles to be inserted into the dialyzer and potted as is known in the art. (Specification, p. 6, lines 22-26.)

Generally, the inlet header 30 design of the present invention increases blood flow in the perimeter region of the fiber bundle 20. As used herein, this means to cause more blood to flow to the perimeter of the fiber bundle than in prior art dialyzer designs that included a standard header design, i.e., a header that does not include any members that modified the flow of the blood as it entered an interior of the dialyzer. The header designs of the present invention reduce the low blood flow zones within the dialyzer header. In this regard, the header designs of the present invention increase blood flow in the perimeter region of the header space where low flows are suspected thus reducing the potential for clot formation. Additionally, these improved flow patterns provide a more complete clearing of blood during rinse back. (Specification, p. 7, lines 3-12.)

Referring now to Figure 2, an embodiment of a header design 40 is illustrated. The header 40 includes an inlet channel 42. In a preferred embodiment, the inlet channel 42 is located in a center of the body 44 of the inlet header 40. The inlet channel 42 defines a fluid flow path that is axial, i.e., in the same direction as the fluid flow of the blood through the fiber bundle 20. (Specification, p. 7, lines 13-17.)

The body 44 also includes a lip member 46 that circumscribes and defines an opening for receiving an end 21 of the dialyzer 10. This allows the header 40 to be sealed on an inlet end 21 of the dialyzer 10. The inlet channel 42 includes an inlet opening 52 and an outlet opening 54.

The inlet opening 52 is placed in fluid communication with a member carrying blood, e.g., a tube. This allows blood to flow from a source, e.g., catheter in a patient, into the inlet opening 52 and out through the outlet opening 54 into an interior of the dialyzer 10. (Specification, p. 7, lines 18-24.)

The body 44 includes, on a top interior surface 55 thereof, a plurality of members that are designed to modify the fluid flow characteristics of blood as it enters an interior of the inlet header 40. In the embodiment illustrated, these members are a number of vanes 58. The vanes 58 extend from a top interior surface 55 of the inlet header 40 downwardly toward the fiber bundle 20. In the preferred embodiment illustrated, the vanes 58 are curved. The curved vanes 58 impart a circular or swirling motion to the blood as it transitions from an axial flow in the inlet channel 42 to a radial flow along the top interior 55 header surface. This allows the blood to remain in motion preventing stagnant zones to form in the perimeter region, as can be observed in standard dialyzers. (Specification, p. 7, line 25 to p. 8, line 2.)

It should be noted that various modifications are possible to the header 40. For example, by varying the header roof height "H" changes in fluid flow can be achieved. Further, in the preferred embodiment illustrated the outlet opening includes a large radius "R" to minimize the sudden expansion of fluid from the inlet channel 42 which can cause recirculation zones in that area. (Specification, p. 8., line 3 -7.)

As illustrated, the header 40 includes eight vanes 58. If desired, more or less vanes 58 can be utilized. However, it is believed that eight may be a preferable number. More than eight vanes 58 can increase flow resistance to the blood. Less than eight vanes can create reduced blood flow velocity between the vanes 58. In this regard, it is desired that the blood, as it enters the inlet header, follows the vanes 58 and not take a straight line path to the wall of lip 44. The design of the header 40 prevents blood from entering the header and running radially outward impinging on the outer wall of the lip 44. This prevents stagnant zones obtaining better distribution of blood on the fibers. (Specification, p. 8, lines 8-16.)

Referring now to Figure 3, the inlet header design is further illustrated. The inlet header 70 includes a similar body structure to the previous header design including an inlet channel 72,

body member 74, and lip 76. Further, the header design includes a plurality of members 78 for modifying the fluid flow of blood as it enters the inlet header. (Specification, p. 8, lines 17-21.)

With respect to the inlet header design of Figure 2, it was observed that two mechanisms exist which tend to reduce the flow velocity as blood moves from the inlet channel to the outer perimeter. First, as the blood enters the dialyzer it begins to flow into the hollow fibers 20. This reduces the mass flow rate of the remaining blood as it approaches the perimeter. Second, the space between the vanes widens with distance from the inlet opening. This creates a larger cross-sectional area through which blood must flow. Since blood velocity equals the mass flow rate divided by the cross-sectional area, an increase in channel size will reduce the blood velocity. (Specification, p. 8, lines 22-29.)

To reduce velocity loss, as illustrated in Figure 3, raised channels 80 are provided. The raised channels 80 have a decreasing cross-sectional area to help alleviate the velocity loss. Additionally, the space between the channels 80 is lowered to just above the cut surface. This provides a higher resistance to flow in this area thereby allowing the blood to flow through the curved channels 80 toward the perimeter with a swirling action. In the inlet header 70, any number of raised channels 80 can be utilized. However, preferably the inlet header 70 includes eight channels 80. (Specification, p. 8, line 30 to p. 9, line 5.)

Referring now to Figure 4, the inlet header 84 is further illustrated. The inlet header includes a plurality of members 86 that are designed to modify the flow of blood as it enters the inlet header 84. Preferably these members are curved vane members 86. However, in addition, a flat disk 88 is incorporated at the bottom of the vane surfaces. The disk 88 functions to divert the inlet jet of blood from the inlet channel to the outer perimeter of the header. This thereby causes blood to flow under the disk 86 to the fiber surfaces. (Specification, p. 9, lines 6-12.)

In the inlet header 84, the combination of the disk 88 and vanes 86 assures a steady swirling flow of blood in the outer regions of the top of the fiber bundle. Thus, the blood is distributed to the perimeter of the bundle before the blood can begin to enter the fiber bundle. This ensures that blood will begin to flow into the outer fibers immediately upon entering the header. It should be noted with respect to this design that it is also possible to use, instead of

vanes 86, channels (such as the channels of Figure 3). Once again, the number of vanes or channels can be modified although eight is preferred. (Specification, p. 9, lines 13-20.)

A number of experiments were performed that demonstrate the desirable effects of the present invention as described, for example, on pages 19-25 of Appellants' Specification.

VI. ISSUES

Would the dialyzer inlet header, the dialyzer, and the dialyzer header as defined by Claims 1 and 3-28 have been novel, or in the alternative, not obvious in view of DE 3435883 A1?

VII. GROUPING OF THE CLAIMS

Appellants argue for the separate patentability of each of the independent claims separate and apart from each other set forth in detail below pursuant to the requirements of 37 C.F.R. § 1.192(7), unless otherwise specified. Appellants also argue for the separate patentability of dependent claims where specified.

VIII. ARGUMENT

A. The Claimed Invention -- Independent Claims

On appeal, Claims 1, 12, and 21 are the sole independent claims. Independent Claims 1, 12 and 21 are provided below as follows:

Independent claim 1 recites a dialyzer inlet header. The dialyzer header includes a body that is designed to be attached to an end of a dialyzer; an inlet channel providing fluid communication from an exterior of the dialyzer to an interior of the dialyzer, the inlet channel defining a fluid flow path that is axial to a fiber bundle located in the interior of the dialyzer; and

at least one member for modifying the fluid flow path of a fluid as it exits the inlet channel, wherein the member includes a curved vane extending from a portion of the body.

As you know, in the United States Patent and Trademark Office, there is a duty of disclosure to disclose prior art that may be relevant to the examination of a U.S. patent. The prior art can be art cited in a co-pending application, art cited in the application, or other art

known to the Applicants or inventors. Can you please advise us with any such prior art that we should bring to the attention of the United States Patent and Trademark Office.Independent claim 12 recites a dialyzer. The dialyzer includes a body defining an interior and having a first end and a second end; a fiber bundle located in the interior; a blood inlet located at the first end and including a fluid flow channel that causes the blood to flow in an axial direction with respect to the fiber bundle; and a member located in juxtaposition and integral to the blood inlet that causes blood to flow to a perimeter region of a first end of the fiber bundle.

Independent claim 21 recites a dialyzer header. The dialyzer header includes a body member having an inlet channel providing fluid communication from an exterior to an interior of the header, the inlet channel defining a fluid path that is axial to a casing of a dialyzer to which the dialyzer head is attached and the body member including a plurality of members that extend from the body member and that impart a circular motion to the fluid as it enters the interior of the header.

B. The Claimed Invention--Dependent Claims

Claims 3-11 depend from claim 1, either directly or indirectly. Claim 3 depends from claim 1 and further recites that the dialyzer inlet header includes eight vanes. Claim 6 depends from claim 1 and further recites that the member for modifying the fluid flow path defines a curved channel that extends into a portion of the body. Claim 7 depends from claim 6 and recites that the dialyzer inlet header includes eight channels.

Claim 8 depends from claim 1 and further recites that the member for modifying the fluid flow path obstructs the flow of fluid as it exits the fluid channel. Claim 9 depends from claim 8 and further recites that the member for modifying the fluid flow path further includes a disk located under an exit opening of the inlet fluid channel. Claim 10 depends from claim 9 and recites that the body includes a plurality of curved vanes. Claim 11 depends from claim 9 and recites that the body includes a plurality of curved channels.

Claim 13 depends from claim 12 and recites that the member is a curved vane that extends from a portion of the body. Claim 16 depends from claim 12 and recites that the member is a curved channel that extends into a portion of the body. Claim 17 depends from claim 12 and recites that the member is a disk located under an exit opening of the inlet fluid

channel. Claim 18 depends from claim 17 and recites that the member includes a plurality of curved vanes. Claim 19 depends from claim 18 and recites that the member includes a plurality of curved channels.

Claim 22 depends from claim 21 and recites that the members include a plurality of curved vanes. Claim 23 depends from claims 20 and recites that the members include a plurality of curved channels. Claim 24 depends from claim 21 and recites that the members include a device that obstructs the flow of the fluid into portions of the interior of the header. Claim 25 depends from claim 24 and recites that the device is a disk located under the inlet channel. Claim 27 depends from claim 21 and recites that the members include eight vanes. Claim 28 depends from claim 21 and recites that the members include eight channels that extend from the body member.

C. The Rejection

Claims 1 and 3-28 have been rejected under 35 U.S.C. § 102 or, in the alternative, under U.S.C. § 103. The Patent Office essentially asserts that the cited art discloses or suggests each of the features of the claimed invention. In this regard, the Patent Office has relied on a sole reference in support of the anticipation or the alternative obviousness rejections.

D. Claims 1 and 3-28 are Novel and Nonobvious

Appellants respectfully submit that the rejections under 35 U.S.C. § 102 and § 103 should be reversed based on the fact that the Patent Office has failed to establish a *prima facie* case of anticipation and obviousness. Appellants submit that the sole reference fails to disclose or suggest the claimed invention.

1. The Applicable Law

"Under 35 U.S.C. § 102, anticipation requires that each and every element of the claimed invention be disclosed in the prior art ..." *Akzo NV v. U.S. International Trade Commission*, 1 U.S.P.Q. 2d 1241, 1245 (Fed. Cir. 1986). The Court of Appeals for the Federal Circuit has held that "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a *single* prior art reference." *Verdegaal Bros. v. Union Oil of California,* 814 F.2d 628, 631 (Fed. Cir. 1988) (*emphasis added*).

The Federal Circuit has held that the legal determination of an obviousness rejection under 35 U.S.C. § 103 is:

> whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made...The foundational facts for the prima facie case of obviousness are: (1) the scope and content of the prior art; (2) the difference between the prior art and the claimed invention; and (3) the level of ordinary skill in the art...Moreover, objective indicia such as commercial success and long felt need are relevant to the determination of obviousness...Thus, each obviousness determination rests on its own facts.

In re Mayne, 41 U.S.P.Q.2d 1451, 1453 (Fed. Cir. 1997).

In making this determination, the Patent Office has the initial burden of proving a *prima facie* case of obviousness. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). This burden may only be overcome "by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings." *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). "If the examination at the initial stage does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent." *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992).

Further, the Federal Circuit has held that it is "impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious." *In re Fritch*, 23 U.S.P.Q.2d 1780, 1784 (Fed. Cir. 1992). "One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention" *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988).

Moreover, the Federal Circuit has held that "obvious to try" is not the proper standard under 35 U.S.C. §103. *Ex parte Goldgaber*, 41 U.S.P.Q.2d 1172, 1177 (Fed. Cir. 1996). "An-obvious-to-try situation exists when a general disclosure may pique the scientist curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result, or that the claim result would be obtained if certain directions were pursued." *In re Eli Lilly and Co.*, 14 U.S.P.Q.2d 1741, 1743 (Fed. Cir. 1990).

2. The Rejections under 35 U.S.C. §102 and §103 Should Be Reversed Because the Patent Office Has Failed to Establish a *Prima Facie* Case of Anticipation and Obviousness

Appellants respectfully submit that the Patent Office has failed to overcome its *prima facie* burden with respect to the rejections of the claimed invention under 35 U.S.C. §102 or alternatively under §103. At the outset, the Patent Office has merely relied on a single reference in support of the rejections. Contrary to the Patent office's position, the anticipation rejection is improper. Further, Appellants do not believe that one skilled in the art would be inclined to modify same to arrive at the claimed invention.

a. The Dialyzer Header Features of the Claimed Invention

Of the pending claims at issue, claims 1, 12 and 21 are the sole independent claims. Claim 1 relates to a dialyzer inlet header that includes a body designed to the attached to an end of a dialyzer; an inlet channel that provides fluid communication from an exterior of the dialyzer to an interior of the dialyzer wherein the inlet channel defines a fluid flow path that is axial to a fiber bundle located in the interior of the dialyzer. The dialyzer inlet header further includes at least one member for modifying the fluid flow path of fluid as it exits the inlet channel wherein the modifying member includes a curved vane that extends from a portion of the body.

Claims 3-11 depend from claim 1, either directly or indirectly. Claim 3 further recites that the dialyzer inlet header includes eight vanes. Claim 6 further recites that the member for modifying the fluid flow path defines a curved channel that extends into a portion of the body. Claim 7 depends from claim 6 and recites that the dialyzer inlet header includes eight channels. Claim 8 further recites that the member for modifying the fluid flow path obstructs the flow of fluid as it exits the fluid channel. Claim 9 depends from claim 8 and further recites that the member for modifying the fluid flow path further includes a disk located under an exit opening of the inlet fluid channel wherein the body can include a plurality of curved vanes (Claim 10) or can include a plurality of curved channels (claim 11).

Independent claim 12 relates to a dialyzer. The dialyzer includes a body; a fiber bundle located in an interior of the body; a blood inlet located at a first end of the body that includes a fluid flow channel that causes blood to flow in an axial direction with respect to the fiber bundle;

and a member located in juxtaposition and integral to the blood inlet that causes blood to flow to a perimeter region of a first end of the fiber bundle.

Claims 13-20 depend directly or indirectly from claim 12. Claim 13 further recites that the member is a curved vane that extends from a portion of the body. Claim 16 further recites that the member is a curved channel that extends into a portion of the body. Claim 17 recites that the member is a disk located under an exit opening of the inlet fluid channel wherein the member can include a plurality of curved vanes (Claim 18) or can include a plurality of curved channels (Claim 19).

Independent claim 21 relates to a dialyzer header. The dialyzer header includes a body member that has an inlet channel for providing fluid communication from an exterior to an interior of the header wherein the inlet channel defines a fluid path that is axial to a casing of a dialyzer to which the dialyzer head is attached. The body member of the dialyzer header includes a plurality of members that extend from the body member and that impart a circular motion to the fluid as it enters the interior of the header.

Claims 22-28 depend from claim 21 either directly or indirectly. Claim 22 further recites that the members include a plurality of curved vanes. Claim 23 further recites that the members include a plurality of curved channels. Claim 24 further recites that the members include a device that obstructs the flow of the fluid into portions of the interior of the header wherein the device is a disk located under the inlet channel (Claim 25), wherein the members can include eight vanes (Claim 27) or can include eight channels (Claim 28).

Appellants have discovered that the improved header design of the present invention can provide and improved blood flow into the interior of the dialyzer and specifically to the fiber bundle. This eliminates, or at least substantially reduces, the zones of low flow thereby reducing the potential for clotting while improving the ability to rinse the header of blood. See, Specification, page 2, lines 15-20. Appellants have demonstrated the desirable flow effects of the improved header design as disclosed in Appellants' specification on pages 19-25.

b. the Cited Reference Fails to anticipate or render obvious the improved header design of the Claimed Invention

Appellants believe that the Patent Office has improperly relied on the sole cited reference in support of the anticipation or the alternative obviousness rejection. Nowhere does the mere sole cited reference disclose or suggest the improved header design features as required by claims 1 and 3-28. Therefore, Appellants believe that the cited reference fails to anticipate and render obvious the claimed invention.

1. The Patent Office has improperly applied the anticipation and obviousness standards

At the outset, Appellants believe that the Patent Office has improperly applied the anticipation and obviousness standards in support of the rejection of claims 1 and 3-28. With respect to anticipation, clearly the intent of the Patent Office was to apply an obviousness standard and not anticipation. Indeed, the Patent Office opines that differences between the claimed invention and the cited reference are "merely a matter of obvious engineering choice" as provided in the Advisory Action dated October 22, 2003, a copy of which is attached hereto as Exhibit C. Thus, at a minimum, the anticipation rejection should be withdrawn and instead claims 1 and 3-28 should be rejected as allegedly obvious in view of the cited art.

Moreover, Appellants believe that the Patent Office has applied an improper legal standard in order to determine whether the claimed invention is obvious or not. In this regard, the Patent Office concludes that "the prior art element [allegedly] performs the function specified in the claim in substantially the same manner as the function is performed by the corresponding element described in the specification." See, Advisory Action, pages 2-3. Clearly, this is not the proper standard for obviousness. Instead, the Patent Office has relied on an infringement standard and even provides a plethora of case cites in support of same. Indeed, obviousness requires a different legal analysis as compared to infringement pursuant to the different statutory requirements for obviousness (e.g., 35 U.S.C. §103) and infringement (e.g., 35 U.S.C. §271). Thus, the alleged obviousness rejection of claims 1 and 3-28 should be reversed as a matter of law.

2. The cited reference fails to disclose or suggest the claimed invention

Despite the fact that the Patent Office has improperly applied both the anticipation and obviousness standards, Appellants believe that the cited art fails to disclose or suggest the claimed invention. Indeed, the sole cited reference is deficient with respect to a number of features of the improved header as claimed. Further, one skilled in the art would not be inclined to modify the cited art to remedy the deficiencies of same.

The dialyzer inlet header of claims 1 and 3-11 is novel and not obvious

Of claims 1, and 3-11, claim 1 is the sole independent claim. Claim 1 recites a dialyzer inlet header that includes, in part, at least one member for modifying the fluid flow path of a fluid as it exits the inlet channel wherein the member includes a curved vane extending from a portion of the body. In contrast, the cited reference merely discloses guide ribs (50) that are integral to an upper plate face of a guide plate (46). See, DE3435883, Abstract. Clearly, the guide plate (46) is a separate part as compared to the closure cap 24 as illustrated in Fig. 1 of the cited reference. Thus, the cited reference at least fails to disclose a curved vane that extends from a portion of the body of the dialyzer inlet header as required by claim 1.

Further, the cited reference fails to disclose additional features of the modifying member as further defined in the dependent claims. For example, claim 3 requires eight vanes that extend from a portion of the body as illustrated in Figure 2 of Appellants' specification. Claim 6 requires a curved channel that extends from the body that can include eight channels as further defined in claim 7 and illustrated in Figure 3 of Appellants' specification. Claims 8, 9, 10 or 11 further recite that the modifying member includes a disk and a number of curved vanes (claim 10) or curved channels (claim 11) as illustrated in Figure 4 of Appellants' specification.

Indeed, the cited reference requires the use of plate in combination with guide ribs in order to purportedly direct flow. Moreover, the guide ribs extend from the plate and not the closure cap where the plate is separately connected to the closure cap as previously discussed. Clearly, this contrasts the additional features as defined in dependent claims 3 and 6-11.

Nor, do Appellants believe that the sole cited reference suggests the improved flow features of the header as claimed. Again, the cited reference is deficient with respect to a

number of structural features as claimed and discussed above. As previously discussed, the improved header as claimed provides a modifying member that can impart a circular motion to fluid in contact with same as the fluid enters the interior of the header. In turn, this can effectively eliminate, or at least substantially reduce, the zones of low flow and thereby reduce the potential for clotting while improving the ability to rinse the header of blood.

In contrast, the DE 3435883 abstract merely states that "liq[uid] flows radially outwards in the upper section, through peripheral gaps or holes, and then radially inwards in the section below the plate." Clearly, this does not suggest a modifying member that can impart a circular motion as claimed. As previously discussed, Appellants have conducted a number of experiments to demonstrate the beneficial effects of the claimed invention. Thus, Appellants do not believe that one skilled in the art would be inclined to remedy the structural and functional deficiencies of the cited reference to arrive at the claimed invention.

The dialyzer of claims 12-20 is novel and not obvious

Of pending claims 12-20, claim 12 is the sole independent claim. Claim 12 recites a dialyzer that includes, in part, a member located in juxtaposition and integral to the blood inlet that causes blood to flow to a perimeter region of a first end of the fiber bundle. The member can include a curved vane (claim 13), a curved channel (claim 16), a disk with a number of curved vanes (claims 17 and 18) or a disk with a number of curved channels (claims 17 and 19) as illustrated in Figs 2-4 of Appellants' specification. As previously discussed, the member acts to impart a circular motion to fluid in contact with same, thus effectively eliminating, or at least substantially reducing, the zones of low flow. In this regard, the potential for clotting can be reduced while improving the ability to rinse the header of blood.

In contrast, the cited reference merely provides a plate that purportedly acts in combination with guide ribs to direct flow in a radial pattern as discussed above. The plate is separately connected to the closure cap where the guide ribs extend from the plate and not the closure cap. Clearly, this is deficient with respect to a member that can impart circular flow to alleviate zones of low flow through the dialyzer. Moreover, the claimed member is in juxtaposition and integral to the blood inlet, such as a curved vane or curved channel that can act

in combination with a disk as further defined in claims 13 and 16-19. Thus, Appellants believe that the cited reference is clearly distinguishable from claims 12-20.

The dialyzer header of claims 21-28 is novel and not obvious

Of pending claims 21-28, claim 21 is the sole independent claim. Claim 21 recites a dialyzer header that includes, in part, a body member that includes a number of members that extend therefrom and that impart a circular motion to the fluid as it enters the interior of the header. The members can include curved vanes or curved channels as further defined in claims 22 and 23 and illustrated in Figures 2 and 3 of Appellants' specification. Alternatively, the members include a disk in combination with eight vanes or eight channels that extend from the body member as further defined in claims 24-28 and illustrated in Figure 4 of Appellants' specification.

At the outset, the abstract of the cited reference merely provides a plate with guide ribs extending therefrom that purportedly act to direct flow in a radial pattern as discussed above. Clearly, this fails to disclose or suggest a number of members that extend from a body member of a dialyzer header to impart circular motion to a fluid that enters the interior of the header as required by claim 21. Again, this can effectively eliminate, or at least substantially reduce, the zones of low flow, and thus reduce the potential for clotting while improving the ability to rinse the header of blood.

Further, the guide ribs of the cited reference extend from the plate that is separately connected to the closure cap. This is clearly structurally different than the members that extend from the body of the header, let alone curved vanes or curved channels, such as eight curved vanes or curved channels as further defined by claims 22, 23, 27 and 28, respectively. Again, the improved structural features as claimed allow the dialyzer header to effectively impart a circular motion to the flow therethrough, thus effectively alleviating zones of low flow. Based on at least these structural and functional differences, Appellants believe that the sole cited reference fails to disclose or suggest the dialyzer header as required by claims 21-28.

Accordingly, Appellants respectfully request that the rejections under 35 U.S.C. § 102 and § 103 be reversed.

IX. CONCLUSION

Appellants' claimed invention set forth in claims 1 and 3-28 is neither taught nor suggested by the cited references, either alone or in combination. The Patent Office has failed to establish a *prima facie* case of anticipation and obviousness with respect to the rejection of the claimed invention. Accordingly, Appellants respectfully submit that the anticipation and obviousness rejections are erroneous in law and in fact and should therefore be reversed by this Board.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY _____

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Date: January 26, 2004

APPENDIX

1. A dialyzer inlet header comprising:

a body that is designed to be attached to an end of a dialyzer;

an inlet channel providing fluid communication from an exterior of the dialyzer to an interior of the dialyzer, the inlet channel defining a fluid flow path that is axial to a fiber bundle located in the interior of the dialyzer; and

at least one member for modifying the fluid flow path of a fluid as it exits the inlet channel, wherein the member includes a curved vane extending from a portion of the body.

3. The dialyzer inlet header of Claim 1 including eight vanes.

4. The dialyzer inlet header of Claim 1 wherein the inlet channel is located at a center of the body.

5. The dialyzer inlet header of Claim 1 wherein the header is sealed to an end of a dialyzer casing.

6. The dialyzer inlet header of Claim 1 wherein the member for modifying the fluid flow path defines a curved channel extending into a portion of the body.

7. The dialyzer inlet header of Claim 6 including eight channels extending into the body.

8. The dialyzer inlet header of Claim 1 wherein the member for modifying the fluid flow path obstructs the flow of fluid as it exits the fluid channel.

9. The dialyzer inlet header of Claim 8 wherein the member for modifying the fluid flow path further includes a disk located under an exit opening of the inlet fluid channel.

10. The dialyzer inlet header of Claim 9 wherein the body includes a plurality of curved vanes.

11. The dialyzer inlet header of Claim 9 wherein the body includes a plurality of curved channels.

12. A dialyzer comprising:

a body defining an interior and having a first end and a second end;

a fiber bundle located in the interior;

a blood inlet located at the first end and including a fluid flow channel that causes the blood to flow in an axial direction with respect to the fiber bundle; and

a member located in juxtaposition and integral to the blood inlet that causes blood to flow to a perimeter region of a first end of the fiber bundle.

13. The dialyzer of Claim 12 wherein the member is a curved vane extending from a portion of the body.

14. The dialyzer of Claim 12 wherein inlet channel is located at a center of the body.

15. The dialyzer of Claim 12 wherein the blood inlet is sealed to an end of the dialyzer body.

16. The dialyzer of Claim 12 wherein the member is a curved channel extending into a portion of the body.

17. The dialyzer of Claim 12 wherein the member is a disk located under an exit opening of the inlet fluid channel.

18. The dialyzer of Claim 17 wherein the member includes a plurality of curved vanes.

19. The dialyzer of Claim 17 wherein the member includes a plurality of curved channels.

20. The dialyzer of Claim 12 including a dialysate inlet and a dialysate outlet that define fluid flow channels that are radial to the fiber bundle.

21. A dialyzer header comprising a body member having an inlet channel providing fluid communication from an exterior to an interior of the header, the inlet channel defining a fluid path that is axial to a casing of a dialyzer to which the dialyzer head is attached and the body member including a plurality of members that extend from the body member and that impart a circular motion to the fluid as it enters the interior of the header.

22. The dialyzer header of Claim 21 wherein the members are a plurality of curved vanes.

23. The dialyzer header of Claim 20 wherein the members are a plurality of curved channels.

24. The dialyzer header of Claim 21 wherein the members include a device that obstructs the flow of the fluid into portions of the interior of the header.

25. The dialyzer header of Claim 24 wherein the device that obstructs is a disk located under the inlet channel.

26. The dialyzer inlet header of Claim 21 wherein inlet channel is located at a center of the body.

27. The dialyzer inlet header of Claim 21 including eight vanes.

28. The dialyzer inlet header of Claim 21 including eight channels extending into the body member.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/871,863	06/01/2001	Randolph H. Watkins	DI-5717	1448

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29200 7590 06/26/2003

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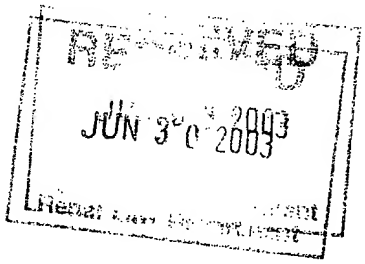

EXAMINER
MENON, KRISHNAN S

ART UNIT	PAPER NUMBER
1723	

DATE MAILED: 06/26/2003

DUE: 9-26-03

Please find below and/or attached an Office communication concerning this application or proceeding.

8/ 13

Office Action Summary	Application N .	Applicant(s)
	09/871,863	WATKINS ET AL.
	Examiner	Art Unit
	Krishnan S Menon	1723

-- The MAILING DATE of this communication appears on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1 and 3-28 are pending.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3-28 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over DE 3435883 A1.

DE '883 teaches a dialyzer inlet header comprising a body (fig 1 and 2), inlet channel providing fluid communication (28) to the interior of the dialyzer and defining a flow path axial to the fiber bundle, one member modifying the fluid flow (fig 2) as it exits the inlet channel as in instant claim(s), and the member includes a curved vane extending from the body as in claim 1. The additional element in Independent claim 21: body member having plurality of members imparting a circular motion is item 50 of fig 2. Independent claim 12 is for a dialyzer having the following elements in addition to that of claim 1: body with first and second end (see figures: only one end shown), fiber bundle (20), blood inlet (28), and the member (fig 2) is integral and in juxtaposition to the blood inlet causing blood to flow to the perimeter.

Re the member including curved vanes being extending from or integral with the body: "...the use of a one piece construction instead of the structure disclosed in [the prior art] would be merely a matter of obvious engineering choice" (*In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965)).

DE '883 teaches additional elements of the dependent claims as follows: Curved vanes (50) and curved channels as in instant claim(s) 6, 10, 11, 13, 16, 18, 19, 22 and 23. Eight vanes and eight channels as in instant claim(s) 3,7, 27 and 28. Inlet channel is located at a center of the body (see fig 1) as in instant claim(s) 4, 14 and 26. Header (blood inlet) is sealed to an end of the dialyzer (see fig

1) as in instant claim(s) 5 and 15. Member includes a disk (46) that obstructs the flow as it exits into portions of the interior of the header as in instant claim(s) 8 and 24. The disc that obstructs the flow is located under the exit opening of the inlet channel as in instant claim(s) 9, 17 and 25. The dialyzate inlet and outlet fluid flow channels are radial to the fiber bundle as in instant claim(s) 20 (see fig 1, 2).

Response to Arguments

Applicant's arguments filed 3/9/03 have been fully considered but they are not persuasive.

Argument re improved header design giving improved flow: need to show supporting evidence that there is an unexpected substantial improvement over the prior art. Re "... the fluid flow path modifying member that extends from and/or is integral to a body..", see the rejection.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S Menon whose telephone number is 703-305-5999. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L Walker can be reached on 703-308-0457. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Krishnan Menon
Patent Examiner
June 17, 2003

Walker
W. L. WALKER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700

Records 1 of 1 In full Format

1. 1/19/1 DIALOG(R)File 351:Derwent WPI (c) 2002 Thomson Derwent. All rts. reserv.

004603859
WPI Acc No: 1986-107203/198617
XRAM Acc No: C86-045816
XRPX Acc No: N86-078889

Directing flow into hollow dialysis fibres by deflector - plate spanning widened end of housing

Patent Assignee: FRESENIUS AG (FREP)
Inventor: HEILMANN K; HOFFMANN R; KRAMP U
Number of Countries: 001 Number of Patents: 002
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week	
DE 3435883	A	19860417	DE 3435883	A	19840929	198617	B
DE 3435883	C	19880714				198828	

Priority Applications (No Type Date): DE 3435883 A 19840929
Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
DE 3435883	A		19		

Abstract (Basic): DE 3435883 C

The ends of a bundle of semi-permeable dialysis fibres (20) are embedded in known manner in a cast polymer layer (22). From a feed pipe (28) in a closure cap (24) liq. for dialysis enters the widened upper end (16) of the cylindrical housing (12). The space (38) between feed pipe mouth and fibre ends is divided into upper and lower sections by a transverse guide plate (46). Liq. flows radially outwards in the upper section, through peripheral gaps or holes, and then radially inwards in the section below the plate. The upper plate face has integral generally radial arcuate guide ribs (50). Gaps between lower plate and polymer layer is maintained by spacers.

USE/ADVANTAGE - For blood dialysis. Avoids dead zones for blood flow between feed pipe and fibres. (19pp Dwg.No.1/3)

Title Terms: DIRECT; FLOW; HOLLOW; DIALYSE; FIBRE; DEFLECT; PLATE; SPAN; WIDE; END; HOUSING
Derwent Class: J01; P34
International Patent Class (Additional): A61M-001/18
File Segment: CPI; EngPI
Manual Codes (CPI/A-N): J01-C03B1

(19) BUNDESREPUBLIK DEUTSCHLAND

DEUTSCHES PATENTAMT

(12) **Offenlegungsschrift**

(11) **DE 3435883 A1**

(51) Int. Cl. 4: **A61M 1/18**

(21) Aktenzeichen: P 34 35 883.8
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DE 3435883 A1

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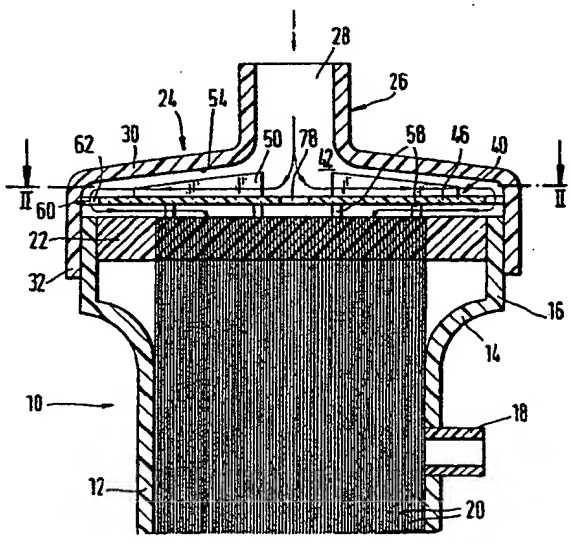
Prüfungsantrag gem. § 44 PatG ist gestellt

(54) Dialysator

Hohlfaserdialysator, der im Zwischenraum zwischen der Endkappe und der Vergußschicht der Hohlfasern eine Strömungsleiteinrichtung aufweist, die sich quer durch den gesamten Zwischenraum erstreckt und am Außenumfang zwischen Abstandshaltern einen ringförmigen Schlitz aufweist, durch den die zugeführte Flüssigkeit strömen kann. Demgemäß wird die Flüssigkeit durch die Strömungsleiteinrichtung zunächst radial nach außen gelenkt und fließt nach dem Durchfließen der Strömungsleiteinrichtung radial nach innen wieder zurück.



DE 3435883 A1

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FRESENIUS AG
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- 11 FR 0810 4/k -

Patentansprüche

1. Dialysator, aufweisend ein röhrenförmiges Gehäuse, das an seinen beiden Enden jeweils durch eine Vergußschicht verschlossen ist, eine Vielzahl von semipermeablen Hohlfasern, die sich durch das Gehäuse und die Vergußschicht hindurcherstrecken, auf die Enden des Gehäuses aufgesetzte Endkappen, die jeweils ein Zuführungsrohr aufweisen, wobei jeweils ein Zwischenraum zwischen der Vergußschicht und der Endkappe gebildet wird, der einerseits mit den Zuführungsrohren und andererseits mit dem Innenraum der Hohlfasern in Fluidverbindung steht, wenigstens einen aus dem Gehäuse austretenden Rohrstutzen und eine im Zwischenraum vorgesehene Strömungsleiteinrichtung, d a d u r c h g e k e n n z e i c h n e t , daß sich die Strömungsleiteinrichtung (40) quer über den Zwischenraum (38) unter Teilung des Zwischenraums in einen ersten und einen zweiten Durchströmraum (42, 44) erstreckt und mindestens im Bereich des Außenumfangs (68) der Strömungsleiteinrichtung (40) ein Strömungspfad (60) vorgesehen ist, der den ersten und zweiten Durchströmraum (42,44)

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miteinander verbindet.

2. Dialysator nach Anspruch 1, dadurch gekennzeichnet, daß die Strömungsleiteinrichtung als Platte (46) ausgebildet ist, die entlang ihres Außenumfangs (68) eine Mehrzahl von Erhebungen (64) unter Bildung von Schlitzen (66) oder eine Mehrzahl von Bohrungen (70) aufweist.

3. Dialysator nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß die Strömungsleiteinrichtung (40) auf der der Vergußschicht (22) zugewandten Unterseite (56) Abstandshalterelemente (58) aufweist.

4. Dialysator nach einem der Ansprüche 1 - 4, dadurch gekennzeichnet, daß die Strömungsleiteinrichtung (40) auf der der Zuführungsöffnung (28) der Endkappe (24) zugewandten Oberfläche eine Mehrzahl von Strömungsleitelementen (50) aufweist.

5. Dialysator nach Anspruch 4, dadurch gekennzeichnet, daß die Strömungsleitelemente (50) eine derart radial nach außen gebogene Form aufweisen, daß sie der Flüssigkeit eine tangentiale Strömungskomponente verleihen.

6. Dialysator nach einem der Ansprüche 1 - 5, dadurch gekennzeichnet, daß die Innenoberfläche des zylinderförmigen Bereichs der Endkappe (24) eine Ringnut (74) aufweist, in die die Erhebungen (64) der Platte (46) eingerastet sind.

7. Dialysator nach einem der Ansprüche 1 - 6, dadurch gekennzeichnet, daß die Strömungsleiteinrichtung (40) eine Entlüftungseinrichtung aufweist.

Patentanwälte/European Patent Attorneys:
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- 11 FR 0810 4/k -

DIALYSATOR

Die Erfindung betrifft einen Dialysator, aufweisend ein röhrenförmiges Gehäuse, das an seinen beiden Enden jeweils durch eine Vergußschicht verschlossen ist, eine Vielzahl von semipermeablen Hohlfasern, die sich durch das Gehäuse und die Vergußschicht hindurcherstrecken, auf die Enden des Gehäuses aufgesetzte Endkappen, die jeweils ein Zuführungsrohr aufweisen, wobei jeweils ein Zwischenraum zwischen der Vergußschicht und der Endkappe gebildet wird, die einerseits mit den Zuführungsrohren und andererseits mit dem Innenraum der Hohlfasern in Fluidverbindung steht, wenigstens einem aus dem Gehäuse austretenden Rohrstutzen und eine im Zwischenraum vorgesehene Strömungsleiteinrichtung.

Aus der US-PS 32 28 877 ist ein derartiger Dialysator bekannt, bei dem beispielsweise Blut über den einen Zuführungsstutzen der einen Endkappe durch den Zwischenraum hindurch dem Hohlraum der Hohlfasern zugeführt und anschließend durch den zweiten Zwischenraum der zweiten Endkappe und durch den Abführungsstutzen hindurch abge-

führt wird. Durch die Poren der semipermeablen Membran erfolgt dann die Entfernung von harnpflichtigen Substanzen bzw. Wasser, sofern eine Dialysebehandlung durchgeführt wird. Andererseits kann jedoch aber auch dem röhrenförmigen Gehäuse über einen Zuführungsstutzen Dialysierflüssigkeit zugeführt werden, die die Außenoberfläche der Hohlfasern umströmt und anschließend aus einem weiteren Stutzen aus dem Rohr abgeschieden wird.

Wie bereits eingangs erwähnt, erstrecken sich die Hohlfasern durch das röhrenförmige Gehäuse und die an den Enden des Gehäuses befindlichen Vergußschichten hindurch, wobei regelmäßig die Hohlfasern nicht unmittelbar an den Gehäuserand geführt sind. So kann beispielsweise das Gehäuse im Randbereich aufgeweitet sein, wie dies beispielsweise aus der US-PS 4 001 110 ersichtlich ist, mit der Folge, daß ein ringförmig umlaufender Randbereich in der Vergußmasse gebildet wird, der nicht von den Hohlfasern durchsetzt ist. Dieser Randbereich steht auch nicht mit der Endkappe in Verbindung, die regelmäßig über das Gehäuse gestülpt ist und anschließend mit dem Gehäuse verbunden wird.

Dieser Randbereich führt insbesondere beim Einsatz als Hämodialysator zu Problemen, da das über den Zuführungsstutzen zugeführte Blut auch in diese Randbereiche strömt und aus diesen nicht abfließen kann, so daß es dort zu einer Gerinnung bzw. Verklumpung des Bluts kommt. Dies hat jedoch zur Folge, daß Hohlfasern während der Dialysebehandlung verstopft werden können und somit nicht mehr für die Dialysebehandlung zur Verfügung stehen.

Andererseits können jedoch aber auch in dem zweiten, stromab gelegenen Zwischenraum sich derartige Verklumpungen bilden, was bei dem Rücktransport des Bluts zum Körper des Patienten nicht unproblematisch ist.

Es wurden daher Versuche unternommen, diesen Randbereich möglichst zu beschränken bzw. zu beseitigen. So wurden beispielsweise Endkappen entwickelt, die eine zweite ringförmig umlaufende Wand aufweisen, die beim Aufsetzen der Endkappe auf das röhrenförmige Gehäuse in der unmittelbaren Nachbarschaft zu den äußeren Hohlfasern zu liegen kommt, so daß im wesentlichen der umlaufende, nicht von den Hohlfasern beaufschlagte Bereich der Vergußschicht beseitigt wird. Da jedoch bei einer derartigen Anordnung innerhalb der Kappe ein ringförmig mit Luft gefüllter Zwischenraum gebildet wird, muß dieser mit einer speziellen Dichtmasse vergossen werden, die über spezielle, in der Endkappe vorgesehene Stutzen zu- und abgeführt werden muß.

Eine derartige Herstellungsweise ist natürlich sehr zeitaufwendig und kostspielig, wobei zusätzlich nicht völlig sichergestellt werden kann, daß sämtliche Randbereiche der Vergußmasse, die nicht von den Hohlfasern durchzogen sind, völlig abgedeckt sind. Demgemäß können also auch bei dieser bekannten Ausführungsform sogen. Totzonen zurückbleiben, in denen auch nach dem Ausspülen mit steriler physiologischer Kochsalzlösung Blutreste zurückbleiben, was für den Benutzer bereits optisch höchst unerwünscht ist.

Zur Beseitigung dieser Probleme wurde bereits in der DE-OS 26 46 358 vorgeschlagen, das Blut über einen tangential zum Gehäuse bzw. zur Endkappe verlaufenden Anschlußstutzen anstelle des koaxial zur Gehäuselängsachse angeordneten Zuführungsstutzens zuzuführen, was bei dem in der DE-OS beschriebenen Dialysator mit zentralem Dialysateinlauf die Probleme mit den Totwasserzonen im wesentlichen beseitigte. Für den eingangs erwähnten Dialysator sind jedoch diese seitlich angeordneten Stutzen praktisch nicht einsetzbar, da sich wiederum Totzonen in dem Zwischenraum bilden.

In der DE-OS 26 46 358 ist in einer weiteren Ausführungsform eine kegelförmige Strömungsleiteinrichtung vorgeschlagen worden, die im wesentlichen den Zentralbereich der Vergußmasse abdeckt, der nicht von den Hohlfasern durchsetzt ist. Andererseits bleibt jedoch wiederum der vorstehend erwähnte ringförmige Außenrand übrig, so daß sich auch hier wiederum Totzonen bilden können.

Der Erfindung liegt daher die Aufgabe zugrunde, einen Dialysator der eingangs erwähnten Art so fortzubilden, daß die in den Randzonen des Zwischenraums zwischen der Vergußschicht und der Endkappe gebildeten Toträume beseitigt werden.

Die Lösung der Aufgabe erfolgt dadurch, daß sich die Strömungsleiteinrichtung quer über den Zwischenraum unter Teilung des Zwischenraums in einen ersten und einen zweiten Durchströmungsraum erstreckt und mindestens im Bereich des Außenumfangs der Strömungsleiteinrichtung ein Strömungspfad vorgesehen ist, der den ersten und zweiten Durchströmungsraum miteinander verbindet.

Mit dem erfindungsgemäßen Dialysator können die eingangs geschilderten Toträume wirksam beseitigt werden, da die Strömungsleiteinrichtung das zuströmende Fluid, insbesondere Blut, so führt, daß die Außenbereiche zwangsläufig durchströmt werden.

Erfindungsgemäß wird das durch den Zuführungsstutzen in den Zwischenraum eingeführte Blut zunächst mit der Strömungsleiteinrichtung in Kontakt gebracht, die dann das Blut im wesentlichen radial nach außen ablenkt, d.h. das Blut wird zunächst nahezu vollständig in den Außenbereich des Zwischenraums verdrängt.

In dem üblicherweise ringförmig umlaufenden Außenbereich des Zwischenraums, der die sonst üblichen, eingangs erwähnten, nicht mehr durchströmten Totbereiche aufweist, sind in der Strömungsleiteinrichtung Strömungspfade in Form von Durchbrechungen, Löchern, Schlitzen u.dgl. vorgesehen, durch die das Blut aus dem ersten Durchströmungsraum in den zweiten Durchströmungsraum abfließt. Die beiden Durchströmungsräume werden bekanntlich im Zwischenraum durch die Anordnung der Strömungsleiteinrichtung gebildet.

Nach dem Durchströmen dieses in der Strömungsleiteinrichtung vorgesehenen Strömungspfades fließt das Blut von außen, d.h. von der ringförmigen Wand der Abdeckkappe oder der Gehäusewand radial nach innen und gelangt dort in die Öffnungen der Hohlfasern, durch die es dann weiterfließt.

Somit wird das Fluid, insbesondere Blut, in dem erfindungsgemäßen Dialysator oder der Separationsvorrichtung mit Hilfe einer Strömungsleiteinrichtung im Zwischenraum zwischen der Abdeckkappe und der Vergußschicht zunächst nach außen gelenkt und kehrt nach dem Durchfließen der Strömungsleiteinrichtung von außen wieder nach innen zurück, mit der Folge, daß der gesamte Zwischenraum praktisch vollständig um- und durchflossen wird.

Als Strömungsleiteinrichtung wird vorteilhafterweise eine Platte verwendet, die in einer ersten Ausführungsform so bemessen ist, daß ihr Durchmesser geringer ist als der Innendurchmesser der Endkappe. Infolgedessen werden beim Einsetzen dieser Platte am Außenumfang Schlitze gebildet, durch die das Blut fließen kann. Des weiteren können vorteilhafterweise gemäß dieser Ausführungsform am Außenumfang Vorsprünge als Abstandshaltereinrichtungen vorgesehen sein, die so bemessen sind, daß sie die Anordnung der Platte in der Endkappe fixieren.

Vorteilhafterweise kann innerhalb der Endkappe eine ringförmige Nut umlaufen, in die die Vorsprünge einrasten, so daß dort vorteilhafterweise die Platte unverlierbar fixiert wird. Gemäß einer solchen Ausführungsform ist der Durchmesser der Platte einschließlich der Länge der Vorsprünge größer als der Innendurchmesser der Endkappe, so daß die Platte nur unter Einwirkung von Kraft in die Endkappe eingesetzt werden kann.

Andererseits ist jedoch aber auch eine Platte denkbar, die lose innerhalb der Endkappe angeordnet ist. In einem solchen Fall ist es vorteilhaft, daß neben den seitlichen Abstandshaltervorsprüngen noch axiale Abstandshaltereinrichtungen sowohl oberhalb als auch unterhalb der Plattenebene angeordnet sind, damit sicher ein erster als auch zweiter Durchströmungsraum gebildet werden. Ansonsten würde die Gefahr bestehen, daß einer dieser Räume durch die Platte dichtgepreßt wird und somit nicht mehr für die Durchströmung zur Verfügung steht.

Weiterhin kann die Strömungsleiteinrichtung vorteilhafterweise auf der dem Zuführungsstutzen zugewandten Oberfläche Strömungsteileinrichtungen aufweisen, die einerseits die zuströmende Flüssigkeit gleichmäßig in radialer Richtung verteilen und andererseits dem zugeführten Flüssigkeitsstrom eine bestimmte Strömungsrichtung aufprägen können. So können diese Strömungsteileinrichtungen der zuströmenden Flüssigkeit infolge ihrer Form eine tangentiale Strömungskomponente aufprägen, wodurch der Aufprall der Flüssigkeit auf die Außenwand gemildert werden kann. In einem derartigen Fall können die Strömungsteileinrichtungen natürlich auch als Abstandshalter für den ersten Durchströmungsraum dienen.

Des weiteren kann zur Verbesserung der Entlüftung des zweiten Durchströmungsraums, d.h. des Raums, bei dem die Flüssigkeit radial von außen nach innen strömt, im Bereich des Zentrums wenigstens eine Öffnung vorgesehen

sein, durch die die Entlüftung in den ersten Durchströmungsraum sichergestellt wird. Da die Flüssigkeit oder das Blut zu Beginn der Einströmphase möglichst gleichmäßig von allen Seiten nach innen strömen soll, kann die Bildung von Luftblasen u.dgl. zu befürchten sein, die stationär im zweiten Durchströmungsraum verbleiben und die einen Teil der Öffnungen der Hohlfasern somit blockieren. Dies wird durch wenigstens eine Öffnung im Zentralbereich der Strömungsleiteinrichtung beseitigt.

Weiterhin ist an sich die Form der Platte unkritisch. Sie kann eben oder aber mit einer erhabenen Struktur ausgebildet sein, wobei die erhabene Struktur die Strömung begünstigen kann. So kann beispielsweise eine Platte mit Kegelstruktur vorteilhafterweise für die erfindungsgemäßen Zwecke eingesetzt werden.

Weitere Einzelheiten, Merkmale und Vorteile der Erfindung sind anhand der nachfolgenden Beschreibung von Ausführungsbeispielen unter Bezugnahme auf die Zeichnung erläutert. Es zeigen:

Fig. 1 einen Teilschnitt durch eine erste Ausführungsform eines erfindungsgemäßen Dialysators gemäß Linie I-I in Fig. 2,

Fig. 2 einen Schnitt durch den Dialysator nach Fig. 1 gemäß Linie II-II in Fig. 1,

Fig. 3 eine vergrößerte Schnittdarstellung durch eine Hälfte der symmetrischen Endkappe einer anderen Ausführungsform eines erfindungsgemäßen Dialysators in einer Fig. 1 entsprechenden Darstellung.

In Fig. 1 ist der Dialysator mit 10 ersichtlich, der aus einem Gehäuse 12 besteht, das sich gemäß der in Fig. 1 gezeigten Ausführungsform in seinem Endbereich 14 aufweitet und wieder in einen zylinderförmigen Abschlußbereich 16 übergeht. Diese Aufweitung ist jedoch nicht

erfindungswesentlich. Dementsprechend kann auch das Gehäuse 12 als glatter Hohlzylinder ausgebildet sein.

In der Nähe des Endbereichs 14 ist im Gehäuse 12 ein rohrförmiger Stutzen 18 vorgesehen, der mit einer Schlauchleitung verbunden werden kann. Üblicherweise sind bei einem derartigen Dialysator 10 zwei Stutzen 18 vorgesehen, die vorteilhafterweise diagonal zueinander angeordnet sind.

In dem Gehäuse 12 ist eine Vielzahl von mikroporösen, semipermeablen Hohlfasern 20 vorgesehen, wie sie üblicherweise bei einem Hohlfaserdialysator zum Einsatz kommen. Auch diese Hohlfasern sind längst bekannt und somit nicht Gegenstand der Erfindung.

Diese Hohlfasern liegen in dem Gehäuse 12 in Form eines dichtgepackten Bündels vor, das gegebenenfalls verwebt sein kann.

Um den Innenraum des Gehäuses 12, das einen ersten von einer ersten Flüssigkeit durchströmten Raum darstellt, von dem Innenraum der Hohlfasern 20 zu trennen, der einen zweiten von einer Flüssigkeit, vorteilhafterweise Blut, durchströmten Raum darstellt, zu trennen, ist der Abschlußbereich 16 des Gehäuses 12 mit einer Vergußschicht 22 aus einem Polymerisat versehen, die von den Hohlfasern 20 durchsetzt ist, wobei die Öffnungen der Hohlfasern 20 nicht mit der Vergußschicht 22 verschlossen sind, also von der Außenoberfläche der Vergußschicht her offen sind.

Eine derartige Anordnung wird dadurch hergestellt, daß man das offene rohrförmige Gehäuse 12 zunächst mit einem Bündel von Hohlfasern 20 versieht, anschließend in den Abschlußbereich des Gehäuses eine flüssige Vergußmasse einführt, diese aushärten läßt und zum Schluß die Außen-

oberfläche der Vergußschicht 22 derart bearbeitet, daß sie einerseits plan ist und andererseits sämtliche Hohlfasern nach außen hin offen sind.

Auf ein derart mit den Hohlfasern 20 bestücktes Gehäuse 12 wird abschließend die in Fig. 3 näher gezeigte Endkappe 24 aufgesetzt, die anschließend mit dem Abschlußbereich 16 des Gehäuses 12 auf übliche Weise sterildicht verschweißt oder verklebt wird.

Diese Endkappe 24 weist einen Zuführungsstutzen 26 mit einer Zuführungsöffnung 28 auf, wobei die Achse des Zuführungsstutzens 26 koaxial zur Längsachse des Gehäuses 12 angeordnet ist.

Von diesem Zuführungsstutzen 26 erstreckt sich die Endkappe 24 über den Kappenbereich 30 nach außen und geht in einen hohlzylinderförmigen Endbereich 32 über, der größtenteils über den Abschlußbereich 16 des Gehäuses 12 geschoben ist, wie dies aus Fig. 3 ersichtlich ist. Mit diesem Endbereich 32 ist die Kappe 24 über die Schweißschicht 34 verbunden.

Wenn die Endkappe 24 auf das Gehäuse 12 aufgesetzt ist, wird zwischen der Oberfläche 36 der Vergußschicht 22 und der Innenoberfläche der aufgesetzten Endkappe 24 ein Zwischenraum 38 gebildet, der durch eine Strömungsleiteinrichtung 40 in einen ersten Durchströmraum 42 und einen zweiten Durchströmraum 44 unterteilt wird.

Die Strömungsleiteinrichtung 40 ist vorteilhafterweise als Platte 46 ausgebildet, deren Durchmesser im wesentlichen dem Innendurchmesser der Endkappe 24 entspricht und die üblicherweise kreisförmig ausgeführt ist. Diese Platte 46 erstreckt sich vorteilhafterweise quer über die der Vergußschicht 22 zugewandte Öffnung der Endkappe 24 und deckt diese im wesentlichen ab.

Wie in Fig. 1 oder 3 gezeigt, ist die Platte 46 im wesentlichen eben. Andererseits kann sie jedoch auch kegelförmig ausgestaltet sein, wobei die Spitze des Kegels vorteilhafterweise zur Zuführungsöffnung 28 ausgerichtet ist.

Vorteilhafterweise sind auf der der Zuführungsöffnung 28 zugewandten Oberfläche 48 der Platte 46 Strömungsleitelemente 50 in Form von Leitschaufeln angeordnet, wie dies aus Fig. 2 ersichtlich ist.

Diese Strömungsleitelemente 50 erstrecken sich in radial gekrümmter Weise, beginnend in der Nachbarschaft des Mittelpunkts der Platte 46, nach außen und enden im Bereich des Randes 52 der Platte 46. Diese Strömungsleitelemente 50 können eine gerade oder - wie in Fig. 2 gezeigt - eine gekrümmte Form aufweisen, wobei die zuletzt genannte Form bevorzugt ist, da sie der zuströmenden Flüssigkeit eine tangentiale Strömungskomponente aufprägen können.

Weiterhin können die Strömungsleitelemente 50 als Abstandshalter zur Innenoberfläche 54 der Endkappe 24 dienen und somit verhindern, daß sich die Platte 54 an der Endkappe 24 anlegt.

Weiterhin weist die Unterseite 56 der Platte 46, die der Vergußschicht 22 zugewandt ist, ebenfalls Abstandshalterelemente 58 auf, die verhindern, daß eine lose eingelegte Platte 46 beim Anströmen durch Flüssigkeit aus der Zuführungsöffnung 28 die Cberfläche 36 der Vergußschicht 22 und damit die Öffnungen der Hohlfasern 20 zusetzt. Diese Abstandshalterelemente 58 sind in Form von punktartigen Erhebungen auf der Unterseite 56 der Platte 46 angeordnet und sind aus Fig. 2 dadurch ersichtlich, da die Platte 46 vorteilhafterweise aus einem transparenten Kunststoffmaterial, wie Polycarbonat, besteht.

Zur Herstellung einer Fluidverbindung zwischen dem ersten Durchströmraum und dem zweiten Durchströmraum 44, also einer Fluidverbindung zwischen der Zuführungsöffnung 28 und den Öffnungen der Hohlfasern 20 durch den Zwischenraum 38, ist am Außenumfang der Strömungsleiteinrichtung 40 ein Strömungspfad 60 vorgesehen, der die beiden Durchströmungsräume 40 und 42 miteinander verbindet. Somit weist die Platte 46 im Einbauzustand an ihrem Außenumfang eine Mehrzahl von Durchbrechungen 62 auf, die - wie aus Fig. 2 und 3 ersichtlich ist - dadurch gebildet werden, daß am Außenumfang der Platte 46 regelmäßig um den Außenumfang verteilt, mehrere radial nach außen vorstehende Erhebungen oder Noppen 64 vorgesehen sind. Die Platte 46 mit den Erhebungen 48 ist dabei so bemessen, daß sie innerhalb der Endkappe 24 im wesentlichen ohne Spiel angeordnet werden kann, d.h. die Erhebungen 64 berühren nahezu die Innenoberfläche des zylindrischen Bereichs der Endkappe 24.

Demzufolge wird der Strömungspfad 60 dadurch gebildet, daß - wie in Fig. 2 strichliert ausschnittsweise gezeigt - ein ringförmiger Schlitz 66 zwischen dem Außenumfang der Platte 46 und der Innenoberfläche des Endbereichs 32 der Endkappe 24 gebildet wird. Dabei entspricht die Schlitzbreite der Höhe der Erhebungen 64, die um den Außenumfang 68 der Platte 46 verteilt sind.

Andererseits kann anstelle dieser Erhebungen 64 der Außenumfang 68 der Platte 46 unmittelbar mit der Innenoberfläche des Endbereichs 32 der Endkappe 24 verbunden sein. Gemäß dieser Ausführungsform, die jedoch weniger bevorzugt ist, sind im Randbereich 68 der Platte 46, wie dies in Fig. 2 strichliert gezeigt ist, Bohrungen 70 vorgesehen, die gleichmäßig um den Randbereich 68 verteilt sind. Wesentlich an dieser Ausführungsform ist lediglich, daß die freie Randzone 72, die durch den Endbereich des Gehäuses 12 und den Endbereich der Vergußschicht 22 gebildet ist, wirksam von der Flüssigkeit an- bzw. durchströmit wird.

Gemäß einer weiteren bevorzugten Ausführungsform ist die Endkappe 26 im Bereich des Zwischenraums 38 auf ihrer Innenoberfläche mit einer umlaufenden Ringnut 74 versehen, an die sich in Richtung auf die der Vergußschicht 22 zugewandte Öffnung der Endkappe 24 eine Einlaufschräge 76 auf der Innenoberfläche des Endbereichs 72 der Endkappe 24 anschließt. Diese Einlaufschräge 76 verengt sich dabei in Richtung auf die Ringnut 74. Hierdurch wird das Einsetzen der Platte 46, die am Außenumfang die Erhebungen 64 aufweist, erleichtert.

Gemäß einer bevorzugten Ausführungsform läßt sich diese Platte paßgenau in die Ringnut 74 unverlierbar einsetzen, wobei die Tiefe der Ringnut nur einen Bruchteil der Höhe der Erhebungen 64 beträgt.

Bei einer derart fixierten Anordnung können natürlich die Abstandshalterelemente 50 bzw. 58 oberhalb und unterhalb der Platte 46 entfallen.

Weiterhin weist die Strömungsleiteinrichtung 40 im Bereich des Zentrums wenigstens eine Entlüftungseinrichtung in Form wenigstens einer Bohrung 78 auf, die derart ausgestaltet ist, daß sie nur einen Bruchteil der zufließenden Flüssigkeit durchläßt, so daß der weit überwiegende Teil über den Strömungspfad 60, der den ersten Durchströmraum mit dem zweiten Durchströmraum miteinander verbindet, abfließt.

Der in Fig. 1 - 3 gezeigte Dialysator wird auf folgende Weise betrieben:

Nachdem der Zuführungsstutzen 26 mit der Blutleitung in Verbindung gebracht worden ist, wird Blut der Zuführungsöffnung 28 zugeführt und gelangt anschließend mit der Strömungsleiteinrichtung 40, insbesondere mit der Platte 46 in Kontakt. Diese Platte 46 leitet vorteilhafterweise mittels der Strömungsleitelemente 50 das Blut nach außen, wie

dies in Fig. 1 durch die pfeilförmig gezeigte Strömungsführung dargestellt ist. Am Außenumfang 68 der Platte 46 gelangt das Blut durch die Durchbrechungen 62 bzw. den ringförmig umlaufenden Schlitz 66 von dem ersten Durchströmraum 42 in den zweiten Durchströmraum 44 und strömt dort radial nach innen, bis es zu den Öffnungen der Hohlfasern 20 gelangt, durch die es anschließend auf die übliche Weise weiterströmt.

Demgemäß wird also das Blut nach der zentralen Zuführung radial nach außen gedrängt und fließt anschließend von außen wieder radial zurück. Dabei kann im zweiten Durchströmraum 44 ein Luftpolster eingeschlossen werden, das durch die in der Platte 46 vorgesehene Bohrung 78 vorteilhafterweise verdrängt werden kann.

Der Dialysator 10 wird vor und nach der Behandlung vorteilhafterweise mit physiologischer Kochsalzlösung gespült, d.h. das Blut wird nach Beendigung der Dialyse wieder vollständig in den Körper des Patienten zurückgeführt. Mit der erfindungsgemäßen Vorrichtung kann der Dialysator 10 vollständig von Blut freigespült werden, da die Totzonen, die bei dem bekannten Dialysator nicht zu reinigen waren, durch die erfindungsgemäße Strömungsleiteinrichtung 40 vollständig durchflossen werden, mit der Folge, daß sich bei der Dialyse kein Blut absetzt und nach Beendigung der Dialyse sämtliche Blutreste aus dem Dialysator 10 entfernt werden können. Des weiteren muß weniger Spüllösung bei dem erfindungsgemäßen Dialysator 10 eingesetzt werden als bei dem bekannten Dialysator, da die Freispülung wesentlich leichter erfolgt.

Weiterhin hat der erfindungsgemäße Dialysator den Vorteil, daß er im wesentlichen handlingsunabhängig ist und auch im wesentlichen keine Pumpstöße durch pulsierende Blutpumpen stören. Insofern läßt sich dieser Dialysator

auch bei niedrigen Strömungsgeschwindigkeiten ohne zusätzliches Abklemmen der flexiblen Zuführungsschläuche, was zur Erhöhung der Blutflußgeschwindigkeit üblicherweise in der Klinik angewandt wird, einsetzen.

– Leerseite –

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FIG. 3

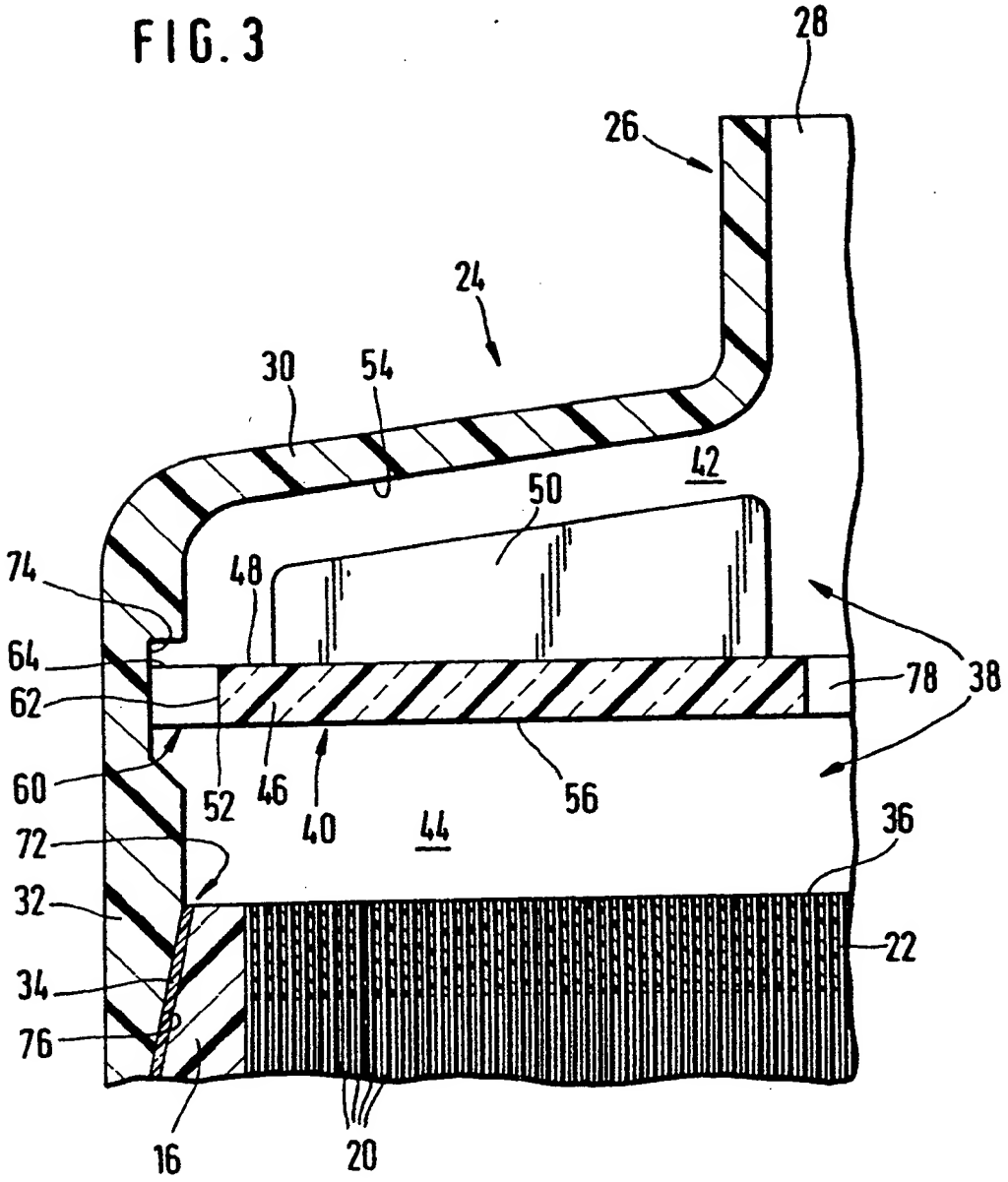

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FIG. 1

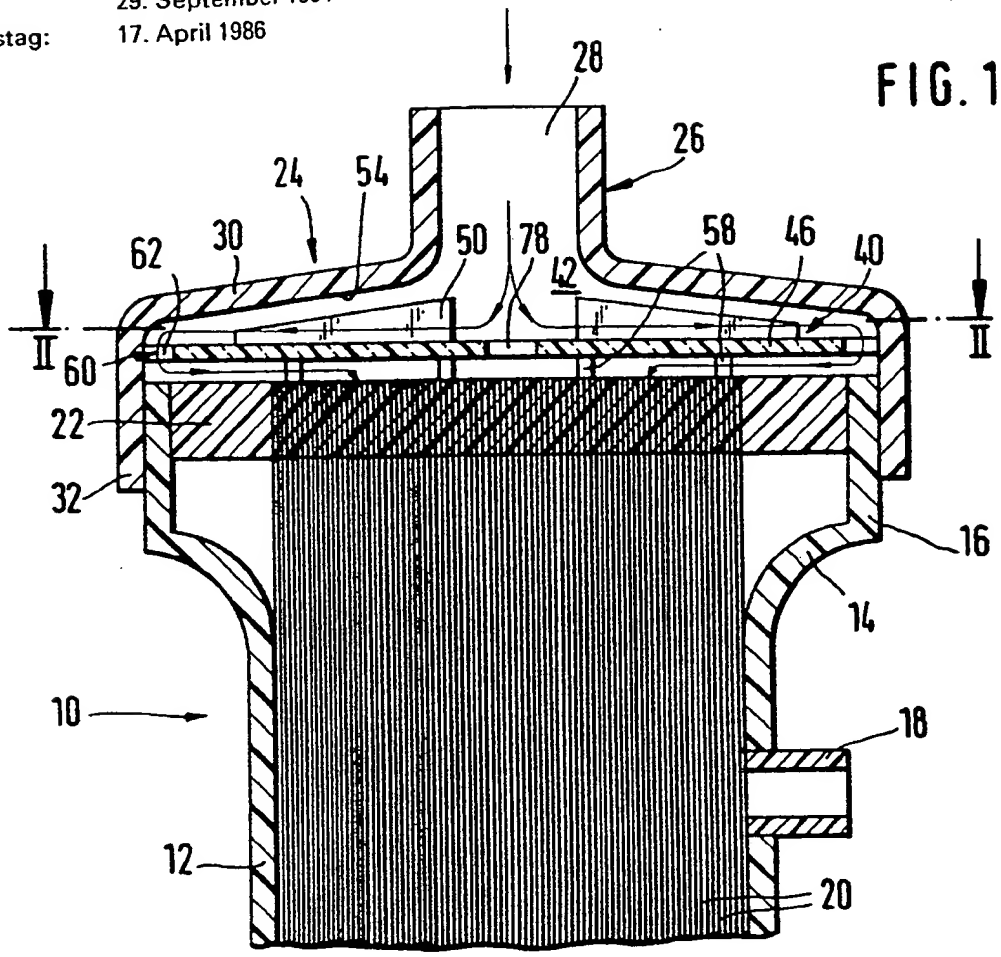


FIG. 2

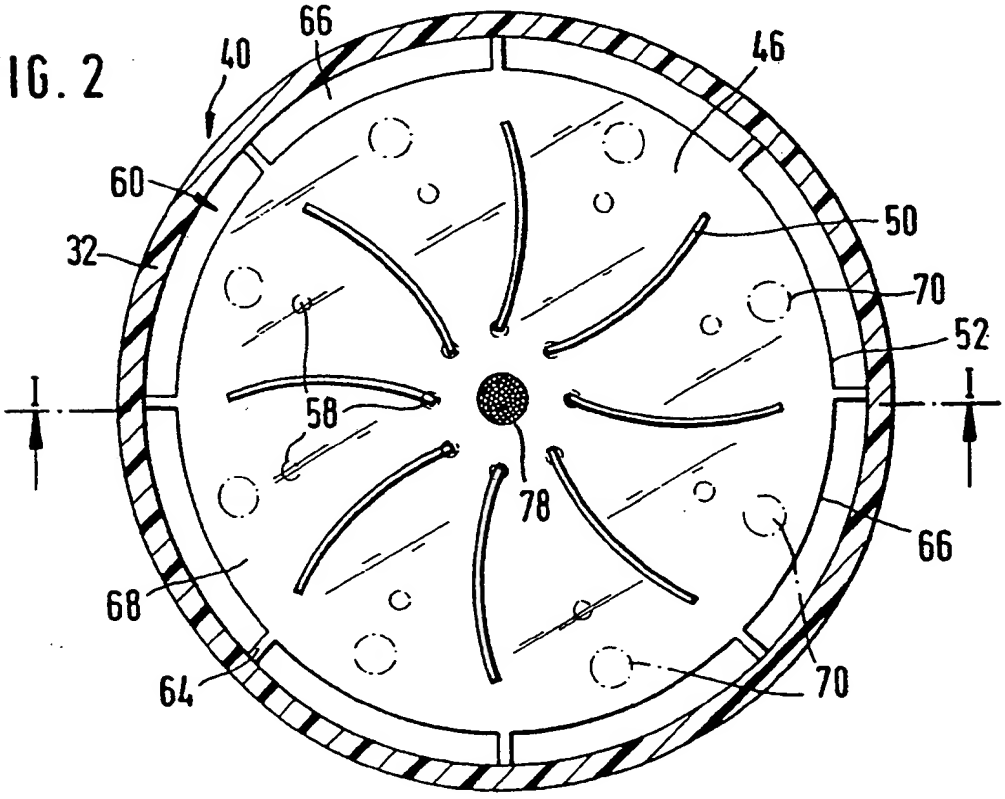


FIG.1

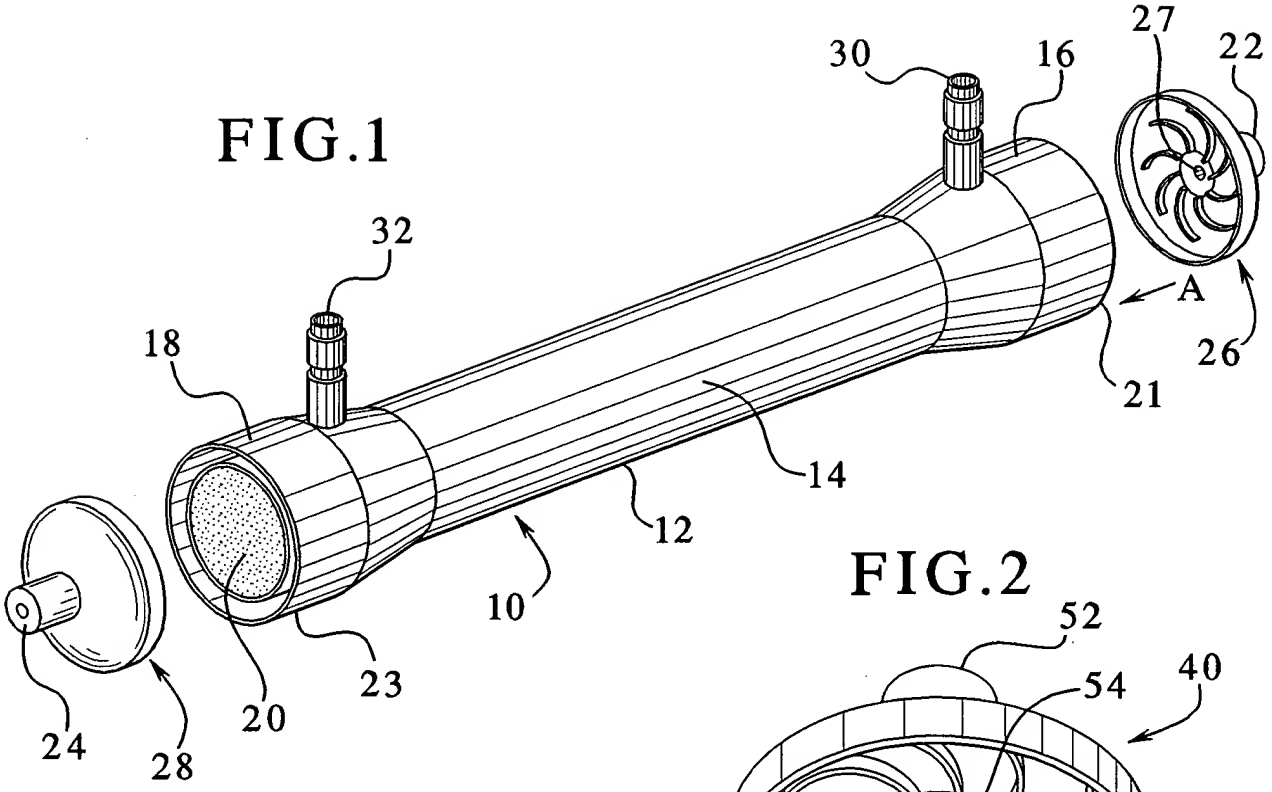


FIG.2

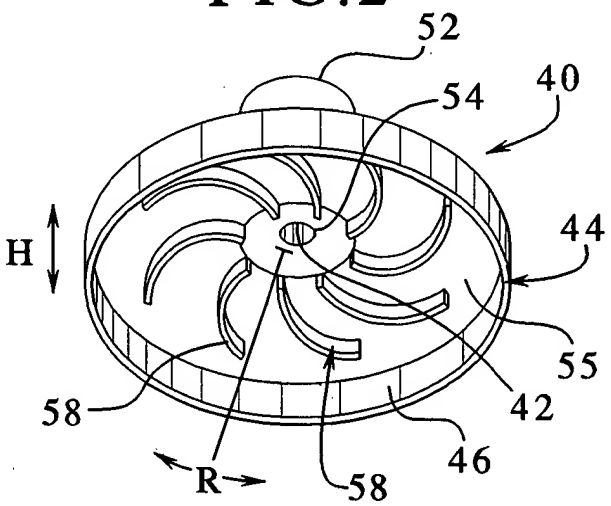


FIG.3

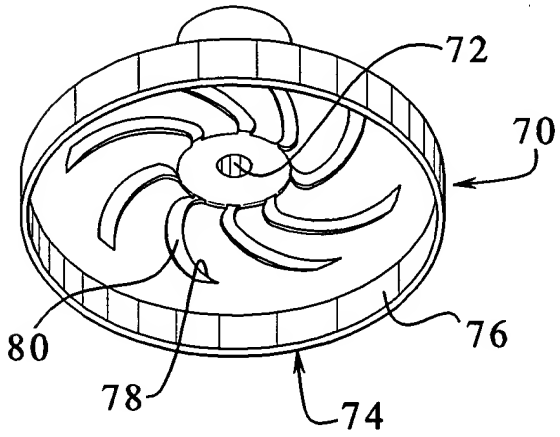
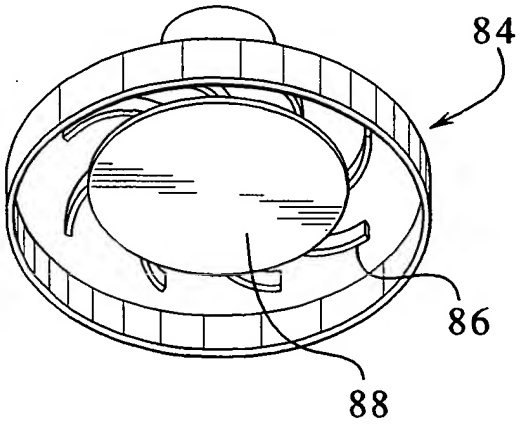


FIG.4



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/871,863	06/01/2001	Randolph H. Watkins	DI-5717	1448

29200 7590 10/22/2003

BAXTER HEALTHCARE CORPORATION
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EXAMINER	
MENON, KRISHNAN S	

ART UNIT	PAPER NUMBER
1723	

DATE MAILED: 10/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

CASE 5717
DKT. DATE ____ SEEN BY ATTY. ____
FINAL DATE 12-25-03 RESP. SENT ____
SUBJECT Advisory Action

PTO-90C (Rev. 10/03)

Advisory Action	Application No. 09/871,863	Applicant(s) WATKINS ET AL.	
	Examiner Krishnan S Menon	Art Unit 1723	

--The MAILING DATE of this communication appears on the cover sheet with the correspondenc ddress --

THE REPLY FILED 29 September 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ they raise the issue of new matter (see Note below);
   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: _____.
3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attac hed Response to Arguments*.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1 and 3-28*.

   Claim(s) withdrawn from consideration: _____.
8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Response to Arguments

Applicant's arguments filed 9/29/03 have been fully considered but they are not persuasive. Argument re 35 USC 102/103 rejection: When the interpretation of the claim(s) is or may be in dispute, i.e., given one interpretation, a rejection under 35 U.S.C. 102 is appropriate and given another interpretation, a rejection under 35 U.S.C. 103(a) is appropriate. See MPEP § § 2111-2116.01 for guidelines on claim interpretation.

Argument re " ... the member including curved vanes being extending from or integral with the body ..." See the case law: *In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965): "...the use of a one piece construction instead of the structure disclosed in [the prior art] would be merely a matter of obvious engineering choice".

Argument re structural difference of the dialyzer header between the claimed invention and the prior art DE 343 5883: In this case, the prior art element:

(A) performs the identical function specified in the claim in substantially the same way, and produces substantially the same results as the corresponding element disclosed in the specification. Kemco Sales, Inc. v. Control Papers Co., 208 F.3d 1352, 54 USPQ2d 1308 (Fed. Cir. 2000)

(B) is not excluded by any explicit definition provided in the specification for an equivalent. A person of ordinary skill in the art would have recognized the interchangeability of the element shown in the prior art for the corresponding element disclosed in the specification. Caterpillar Inc. v. Deere & Co., 224 F.3d 1374, 56 USPQ2d 1305 (Fed. Cir. 2000); Al-Site Corp. v. VSI Int'l, Inc., 174 F.3d 1308, 1316, 50 USPQ2d 1161, 1165 (Fed. Cir. 1999); Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus. Inc., 145 F.3d 1303, 1309, 46 USPQ2d 1752, 1757 (Fed. Cir. 1998); Lockheed

Aircraft Corp. v. United States , 193 USPQ 449, 461 (Ct. Cl. 1977); Data Line Corp. v. Micro Technologies, Inc., 813 F.2d 1196, 1 USPQ2d 2052 (Fed. Cir. 1987).

(C) is an equivalent of the claimed element. There are insubstantial differences between the prior art element and the corresponding element disclosed in the specification. IMS Technology, Inc. v. Haas Automation, Inc., 206 F.3d 1422, 1436, 54 USPQ2d 1129, 1138 (Fed. Cir. 2000); Warner-Jenkinson Co. v. Hilton Davis Chemical Co., 117 S. Ct. 1040, 41 USPQ2d 1865, 1875 (1997); Valmont Industries, Inc. v. Reinke Mfg. Co., 983 F.2d 1039, 25 USPQ2d 1451 (Fed. Cir. 1993). See also Caterpillar Inc. v. Deere & Co., 224 F.3d 1374, 56 USPQ2d 1305 (Fed. Cir. 2000) the prior art element is a structural equivalent of the corresponding element disclosed in the specification. In re Bond, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990). That is, the prior art element performs the function specified in the claim in substantially the same manner as the function is performed by the corresponding element described in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S Menon whose telephone number is 703-305-5999. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L Walker can be reached on 703-308-0457. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Krishnan Menon
Patent Examiner

JOSEPH DRODGE
PRIMARY EXAMINER

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant(s):	Watkins et al.
Appl. No.:	09/871,863
Conf. No.:	1448
Filed:	June 1, 2001
Title:	HEMODIALYZER HEADERS
Art Unit:	1723
Examiner:	K. Menon
Docket No.:	DI-5717 US

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' APPEAL BRIEF

Dear Sir:

This Appeal Brief is submitted in support of the Notice of Appeal submitted by Appellants on November 25, 2003 in the above-identified patent application. This Appeal is taken from the Final Rejection dated June 26, 2003.

I. REAL PARTY IN INTEREST

The real party in interest for the above-identified patent application on Appeal is Baxter International Inc. by virtue of an Assignment recorded at the United States Patent and Trademark Office.

II. RELATED APPEALS AND INTERFERENCES

Appellants do not believe there are any known appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision with respect to the above-identified Appeal.

III. STATUS OF THE CLAIMS

Claims 1 and 3-28 are pending in this application. A copy of appealed Claims 1 and 3-28 is attached in the appendix. In the Final Office dated June 26, 2003, claims 1 and 3-28 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over DE 3435883 A1. A copy of the Final Office Action is appended hereto as Exhibit A of the Supplemental Appendix and a copy of the cited reference is appended hereto as Exhibit B of the Supplemental Appendix.

IV. STATUS OF THE AMENDMENTS

No Amendments After Final were filed.

V. SUMMARY OF THE INVENTION

The present invention relates generally to methods of providing therapies. More specifically, the present invention relates to methods and devices for providing dialysis. (Specification, p. 1, lines 6-8.)

Due to diseases, insult or other causes, the renal system can fail. In renal failure of any cause, there are several physiological derangements. The balance of water, minerals (Na, K, Cl, Ca, P, Mg, SO_4) and the excretion of daily metabolic load of fixed hydrogen ions is no longer possible in renal failure. During renal failure, toxic end products of nitrogen metabolism (urea, creatinine, uric acid, and others) can accumulate in blood and tissues. (Specification, p.1., lines 9-14.)

Dialysis processes have been devised for the separation of elements in a solution by diffusion across a semi-permeable membrane (diffusive solute transport) down a concentration gradient. Principally, dialysis comprises two methods: hemodialysis; and peritoneal dialysis. (Specification, p. 1, lines 15-18.)

Hemodialysis treatment utilizes the patient's blood to remove waste, toxins, and excess water from the patient. The patient is connected to a hemodialysis machine and the patient's blood is pumped through the machine. Catheters are inserted into the patient's veins and arteries to connect the blood flow to and from the hemodialysis machine. Waste, toxins, and excess water are removed from the patient's blood and the blood is infused back into the patient.

Hemodialysis treatments last several hours and are generally performed in a treatment center about three to four times per week. (Specification, p. 1, lines 19-25.)

Hemodialysis typically involves the use of a dialyzer. Dialyzers generally comprise a housing or casing. Located within the interior of the casing is a fiber bundle. Typically the fiber bundle is comprised of a number of membranes that are oriented parallel to each other. The membranes are designed to allow blood to flow therethrough with dialysate flowing on the outside of the membranes. Due to an osmotic gradient that is created, waste products are removed from the blood through the membranes into the dialysate. (Specification, p.1, lines 26-32.)

Accordingly, dialyzers typically include a blood inlet and a blood outlet. The blood inlet is designed to cause blood to enter the fiber membranes and flow therethrough. Dialysate is designed to flow through an inlet of the dialyzer and out of the dialyzer through an outlet. The dialysate is designed to flow across the outside or exterior walls of the membranes. (Specification, p. 2, lines 1-5.)

One of the issues with prior dialyzers is that the flow of the blood through the fiber bundles may not be entirely satisfactory. In this regard, blood may not flow sufficiently through the entire fiber bundle. Rather, there often occurs clotting in areas of low or no flow. For a cylindrical dialyzer, these areas are usually found along the outer perimeter of the surface in which the fibers are embedded. (Specification, p. 2, lines 6-10.)

The present invention relates generally to dialyzers for use in dialysis therapies. More specifically, the present invention relates to dialyzers having an improved header design providing an improved flow of blood into the interior of the dialyzer and specifically to the fiber bundle. This eliminates, or at least substantially reduces, the zones of low flow thereby reducing the potential for clotting while improving the ability to rinse the header of blood. (Specification, p. 2, lines 15-20.)

To this end, the present invention provides a dialyzer inlet header comprising a body that defines, at least in part, an end of the dialyzer. The inlet header includes an inlet channel providing fluid communication from an exterior of the dialyzer to an interior of the dialyzer, the

inlet channel defining a fluid flow path that is axial to a fiber bundle located in the interior of the dialyzer. The dialyzer also includes at least one member for modifying the fluid flow path of a fluid as it exits the inlet channel. The member for modifying the fluid flow path includes a curved vane extending from a portion of the body of the inlet header. For example, the dialyzer inlet header can include eight vanes. (Specification, p. 2, lines 21-24.)

The inlet channel can be located at a center of the inlet header body, and where the inlet header can be sealed to an end of a dialyzer casing. The member for modifying the fluid flow path can also includes a curved channel extending into a portion of the inlet header body, where, for example, the dialyzer inlet header includes eight channels extending into the body such that the member obstructs the flow of fluid as it exits the inlet fluid channel. (Specification, p. 2, line 30 to p. 3, line 6.)

The member can include a disk located under an exit opening of the inlet fluid channel, where for example the inlet header body includes a plurality of curved vanes and further, the body can include a plurality of curved channels. (Specification, p. 3, lines 7-10.)

The present invention provides a dialyzer. The dialyzer includes a body defining an interior and having a first end and a second end, and a fiber bundle located in the interior. A blood inlet is located at the first end of the dialyzer and includes a fluid flow channel that causes the blood to flow in an axial direction with respect to the fiber bundle. A member is located in juxtaposition to the blood inlet that causes blood to flow to a perimeter region of a first end of the fiber bundle as it enters the dialyzer. (Specification, p. 3, lines 11-17.)

The member for modifying the fluid flow path is a curved vane extending from a portion of the inlet header body. This can define a curved channel extending into a portion of the inlet header body. For example, the member for modifying is a disk located under an exit opening of the inlet fluid channel. (Specification, p. 3, lines 18-23.)

A dialyzer header is also provided that includes a body member having an inlet channel providing fluid communication from an exterior to an interior of the header. The inlet channel defining a fluid path that is axial to a body of a dialyzer to which the dialyzer head is attached and the body member including a plurality of members that impart a circular motion to the fluid as it enters the interior of the header. (Specification, p. 3, lines 24-29.)

The members can include a plurality of curved vanes, or for example, the members are a plurality of curved channels. In this regard, the member can obstruct the flow of fluid from the inlet channel as it enters the interior of the header where, for example, the member that obstructs is a disk located under the inlet channel. (Specification, p. 3, line 30 to p. 4, line 3.)

The present invention provides improved dialyzers for providing dialysis to a patient. Although the present invention is designed for use in hemodialysis, the present invention can be used in other and non-traditional therapies. Such methods include, for example, continuous flow or regeneration therapies which may or may not include hemodialysis, for example, continuous flow peritoneal dialysis. Further, although the present invention is designed to be utilized for hemodialysis in patients having chronic kidney disease or failure and therefore require regular treatments, the present invention can be utilized for acute dialysis therapy, for example, in an emergency room setting. (Specification, p. 5, lines 11-19.)

A further discussion of the present invention is provided below and illustrative thereof with references made to Figures 1-4, a copy of which are provided on a single sheet in Exhibit C. Referring now to Figure 1, a dialyzer 10 is generally illustrated. The dialyzer 10 includes a body member 12 that generally includes a casing. The casing includes a core 14 section as well as two bell members 16 and 18 located at each end of the dialyzer 10. Located within the core or casing is a fiber bundle 20. (Specification, p. 5, lines 20-23.)

Located at a first end 21 of the dialyzer 10 is a fluid inlet 22 and at a second end 23 a fluid outlet 24. The fluid inlet 22 and fluid outlet 24 are defined by a fluid inlet header 26 and a fluid outlet header 28, respectively. Generally, the fluid inlet header 26 is designed to allow blood, or other fluid, to flow into an interior of the dialyzer 10 through the fiber bundle 20. The fluid outlet 24 is designed to allow the dialyzed blood, or other fluid, to flow out of the dialyzer 10. As illustrated, blood flows into the dialyzer in an axial direction "A." As used herein, axial means that the blood flow into the dialyzer 10, and specifically the inlet channel 27 of the inlet header 26, is in the same direction as the flow of blood through the fiber bundles 20. (Specification, p. 6, lines 4-12.)

As further illustrated, the dialyzer body 10 includes a dialysate inlet 30 and a dialysate outlet 32. In the embodiment illustrated, the dialysate inlet 30 and dialysate outlet 32 define fluid

flow channels that are in a radial direction, i.e., perpendicular to the fluid flow path of the blood through the fiber bundle 20. The dialysate inlet 30 and dialysate outlet 32 are designed to allow dialysate to flow into the interior of the dialyzer 10 bathing the exterior surface of the fibers in the fiber bundle 20 and then out through the outlet 32. As is known in the art, this causes waste and other toxins to be removed from the blood through the semipermeable membrane of the fibers and carried away by the dialysate. (Specification, p. 6, lines 13-21.)

If desired, the dialyzer 10 can be one integral piece. In this regard, the inlet header 26 and outlet header 28 can be integrally molded to the remaining portions of the dialyzer body 12. However, in a preferred embodiment, the dialyzer headers 26 and 28 are sealed to the first and second end of the dialyzer body 10. This allows the fiber bundles to be inserted into the dialyzer and potted as is known in the art. (Specification, p. 6, lines 22-26.)

Generally, the inlet header 30 design of the present invention increases blood flow in the perimeter region of the fiber bundle 20. As used herein, this means to cause more blood to flow to the perimeter of the fiber bundle than in prior art dialyzer designs that included a standard header design, i.e., a header that does not include any members that modified the flow of the blood as it entered an interior of the dialyzer. The header designs of the present invention reduce the low blood flow zones within the dialyzer header. In this regard, the header designs of the present invention increase blood flow in the perimeter region of the header space where low flows are suspected thus reducing the potential for clot formation. Additionally, these improved flow patterns provide a more complete clearing of blood during rinse back. (Specification, p. 7, lines 3-12.)

Referring now to Figure 2, an embodiment of a header design 40 is illustrated. The header 40 includes an inlet channel 42. In a preferred embodiment, the inlet channel 42 is located in a center of the body 44 of the inlet header 40. The inlet channel 42 defines a fluid flow path that is axial, i.e., in the same direction as the fluid flow of the blood through the fiber bundle 20. (Specification, p. 7, lines 13-17.)

The body 44 also includes a lip member 46 that circumscribes and defines an opening for receiving an end 21 of the dialyzer 10. This allows the header 40 to be sealed on an inlet end 21 of the dialyzer 10. The inlet channel 42 includes an inlet opening 52 and an outlet opening 54.

The inlet opening 52 is placed in fluid communication with a member carrying blood, e.g., a tube. This allows blood to flow from a source, e.g., catheter in a patient, into the inlet opening 52 and out through the outlet opening 54 into an interior of the dialyzer 10. (Specification, p. 7, lines 18-24.)

The body 44 includes, on a top interior surface 55 thereof, a plurality of members that are designed to modify the fluid flow characteristics of blood as it enters an interior of the inlet header 40. In the embodiment illustrated, these members are a number of vanes 58. The vanes 58 extend from a top interior surface 55 of the inlet header 40 downwardly toward the fiber bundle 20. In the preferred embodiment illustrated, the vanes 58 are curved. The curved vanes 58 impart a circular or swirling motion to the blood as it transitions from an axial flow in the inlet channel 42 to a radial flow along the top interior 55 header surface. This allows the blood to remain in motion preventing stagnant zones to form in the perimeter region, as can be observed in standard dialyzers. (Specification, p. 7, line 25 to p. 8, line 2.)

It should be noted that various modifications are possible to the header 40. For example, by varying the header roof height "H" changes in fluid flow can be achieved. Further, in the preferred embodiment illustrated the outlet opening includes a large radius "R" to minimize the sudden expansion of fluid from the inlet channel 42 which can cause recirculation zones in that area. (Specification, p. 8., line 3 -7.)

As illustrated, the header 40 includes eight vanes 58. If desired, more or less vanes 58 can be utilized. However, it is believed that eight may be a preferable number. More than eight vanes 58 can increase flow resistance to the blood. Less than eight vanes can create reduced blood flow velocity between the vanes 58. In this regard, it is desired that the blood, as it enters the inlet header, follows the vanes 58 and not take a straight line path to the wall of lip 44. The design of the header 40 prevents blood from entering the header and running radially outward impinging on the outer wall of the lip 44. This prevents stagnant zones obtaining better distribution of blood on the fibers. (Specification, p. 8, lines 8-16.)

Referring now to Figure 3, the inlet header design is further illustrated. The inlet header 70 includes a similar body structure to the previous header design including an inlet channel 72,

body member 74, and lip 76. Further, the header design includes a plurality of members 78 for modifying the fluid flow of blood as it enters the inlet header. (Specification, p. 8, lines 17-21.)

With respect to the inlet header design of Figure 2, it was observed that two mechanisms exist which tend to reduce the flow velocity as blood moves from the inlet channel to the outer perimeter. First, as the blood enters the dialyzer it begins to flow into the hollow fibers 20. This reduces the mass flow rate of the remaining blood as it approaches the perimeter. Second, the space between the vanes widens with distance from the inlet opening. This creates a larger cross-sectional area through which blood must flow. Since blood velocity equals the mass flow rate divided by the cross-sectional area, an increase in channel size will reduce the blood velocity. (Specification, p. 8, lines 22-29.)

To reduce velocity loss, as illustrated in Figure 3, raised channels 80 are provided. The raised channels 80 have a decreasing cross-sectional area to help alleviate the velocity loss. Additionally, the space between the channels 80 is lowered to just above the cut surface. This provides a higher resistance to flow in this area thereby allowing the blood to flow through the curved channels 80 toward the perimeter with a swirling action. In the inlet header 70, any number of raised channels 80 can be utilized. However, preferably the inlet header 70 includes eight channels 80. (Specification, p. 8, line 30 to p. 9, line 5.)

Referring now to Figure 4, the inlet header 84 is further illustrated. The inlet header includes a plurality of members 86 that are designed to modify the flow of blood as it enters the inlet header 84. Preferably these members are curved vane members 86. However, in addition, a flat disk 88 is incorporated at the bottom of the vane surfaces. The disk 88 functions to divert the inlet jet of blood from the inlet channel to the outer perimeter of the header. This thereby causes blood to flow under the disk 86 to the fiber surfaces. (Specification, p. 9, lines 6-12.)

In the inlet header 84, the combination of the disk 88 and vanes 86 assures a steady swirling flow of blood in the outer regions of the top of the fiber bundle. Thus, the blood is distributed to the perimeter of the bundle before the blood can begin to enter the fiber bundle. This ensures that blood will begin to flow into the outer fibers immediately upon entering the header. It should be noted with respect to this design that it is also possible to use, instead of

vanes 86, channels (such as the channels of Figure 3). Once again, the number of vanes or channels can be modified although eight is preferred. (Specification, p. 9, lines 13-20.)

A number of experiments were performed that demonstrate the desirable effects of the present invention as described, for example, on pages 19-25 of Appellants' Specification.

VI. ISSUES

Would the dialyzer inlet header, the dialyzer, and the dialyzer header as defined by Claims 1 and 3-28 have been novel, or in the alternative, not obvious in view of DE 3435883 A1?

VII. GROUPING OF THE CLAIMS

Appellants argue for the separate patentability of each of the independent claims separate and apart from each other set forth in detail below pursuant to the requirements of 37 C.F.R. § 1.192(7), unless otherwise specified. Appellants also argue for the separate patentability of dependent claims where specified.

VIII. ARGUMENT

A. The Claimed Invention -- Independent Claims

On appeal, Claims 1, 12, and 21 are the sole independent claims. Independent Claims 1, 12 and 21 are provided below as follows:

Independent claim 1 recites a dialyzer inlet header. The dialyzer header includes a body that is designed to be attached to an end of a dialyzer; an inlet channel providing fluid communication from an exterior of the dialyzer to an interior of the dialyzer, the inlet channel defining a fluid flow path that is axial to a fiber bundle located in the interior of the dialyzer; and

at least one member for modifying the fluid flow path of a fluid as it exits the inlet channel, wherein the member includes a curved vane extending from a portion of the body.

As you know, in the United States Patent and Trademark Office, there is a duty of disclosure to disclose prior art that may be relevant to the examination of a U.S. patent. The prior art can be art cited in a co-pending application, art cited in the application, or other art

known to the Applicants or inventors. Can you please advise us with any such prior art that we should bring to the attention of the United States Patent and Trademark Office.Independent claim 12 recites a dialyzer. The dialyzer includes a body defining an interior and having a first end and a second end; a fiber bundle located in the interior; a blood inlet located at the first end and including a fluid flow channel that causes the blood to flow in an axial direction with respect to the fiber bundle; and a member located in juxtaposition and integral to the blood inlet that causes blood to flow to a perimeter region of a first end of the fiber bundle.

Independent claim 21 recites a dialyzer header. The dialyzer header includes a body member having an inlet channel providing fluid communication from an exterior to an interior of the header, the inlet channel defining a fluid path that is axial to a casing of a dialyzer to which the dialyzer head is attached and the body member including a plurality of members that extend from the body member and that impart a circular motion to the fluid as it enters the interior of the header.

B. The Claimed Invention--Dependent Claims

Claims 3-11 depend from claim 1, either directly or indirectly. Claim 3 depends from claim 1 and further recites that the dialyzer inlet header includes eight vanes. Claim 6 depends from claim 1 and further recites that the member for modifying the fluid flow path defines a curved channel that extends into a portion of the body. Claim 7 depends from claim 6 and recites that the dialyzer inlet header includes eight channels.

Claim 8 depends from claim 1 and further recites that the member for modifying the fluid flow path obstructs the flow of fluid as it exits the fluid channel. Claim 9 depends from claim 8 and further recites that the member for modifying the fluid flow path further includes a disk located under an exit opening of the inlet fluid channel. Claim 10 depends from claim 9 and recites that the body includes a plurality of curved vanes. Claim 11 depends from claim 9 and recites that the body includes a plurality of curved channels.

Claim 13 depends from claim 12 and recites that the member is a curved vane that extends from a portion of the body. Claim 16 depends from claim 12 and recites that the member is a curved channel that extends into a portion of the body. Claim 17 depends from claim 12 and recites that the member is a disk located under an exit opening of the inlet fluid

channel. Claim 18 depends from claim 17 and recites that the member includes a plurality of curved vanes. Claim 19 depends from claim 18 and recites that the member includes a plurality of curved channels.

Claim 22 depends from claim 21 and recites that the members include a plurality of curved vanes. Claim 23 depends from claims 20 and recites that the members include a plurality of curved channels. Claim 24 depends from claim 21 and recites that the members include a device that obstructs the flow of the fluid into portions of the interior of the header. Claim 25 depends from claim 24 and recites that the device is a disk located under the inlet channel. Claim 27 depends from claim 21 and recites that the members include eight vanes. Claim 28 depends from claim 21 and recites that the members include eight channels that extend from the body member.

C. The Rejection

Claims 1 and 3-28 have been rejected under 35 U.S.C. § 102 or, in the alternative, under U.S.C. § 103. The Patent Office essentially asserts that the cited art discloses or suggests each of the features of the claimed invention. In this regard, the Patent Office has relied on a sole reference in support of the anticipation or the alternative obviousness rejections.

D. Claims 1 and 3-28 are Novel and Nonobvious

Appellants respectfully submit that the rejections under 35 U.S.C. § 102 and § 103 should be reversed based on the fact that the Patent Office has failed to establish a *prima facie* case of anticipation and obviousness. Appellants submit that the sole reference fails to disclose or suggest the claimed invention.

1. The Applicable Law

"Under 35 U.S.C. § 102, anticipation requires that each and every element of the claimed invention be disclosed in the prior art ..." *Akzo NV v. U.S. International Trade Commission*, 1 U.S.P.Q. 2d 1241, 1245 (Fed. Cir. 1986). The Court of Appeals for the Federal Circuit has held that "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a *single* prior art reference." *Verdegaal Bros. v. Union Oil of California,* 814 F.2d 628, 631 (Fed. Cir. 1988) (*emphasis added*).

The Federal Circuit has held that the legal determination of an obviousness rejection under 35 U.S.C. § 103 is:

> whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made...The foundational facts for the prima facie case of obviousness are: (1) the scope and content of the prior art; (2) the difference between the prior art and the claimed invention; and (3) the level of ordinary skill in the art...Moreover, objective indicia such as commercial success and long felt need are relevant to the determination of obviousness...Thus, each obviousness determination rests on its own facts.

In re Mayne, 41 U.S.P.Q.2d 1451, 1453 (Fed. Cir. 1997).

In making this determination, the Patent Office has the initial burden of proving a *prima facie* case of obviousness. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). This burden may only be overcome "by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings." *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). "If the examination at the initial stage does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent." *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992).

Further, the Federal Circuit has held that it is "impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious." *In re Fritch*, 23 U.S.P.Q.2d 1780, 1784 (Fed. Cir. 1992). "One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention" *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988).

Moreover, the Federal Circuit has held that "obvious to try" is not the proper standard under 35 U.S.C. §103. *Ex parte Goldgaber*, 41 U.S.P.Q.2d 1172, 1177 (Fed. Cir. 1996). "An-obvious-to-try situation exists when a general disclosure may pique the scientist curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result, or that the claim result would be obtained if certain directions were pursued." *In re Eli Lilly and Co.*, 14 U.S.P.Q.2d 1741, 1743 (Fed. Cir. 1990).

2. The Rejections under 35 U.S.C. §102 and §103 Should Be Reversed Because the Patent Office Has Failed to Establish a *Prima Facie* Case of Anticipation and Obviousness

Appellants respectfully submit that the Patent Office has failed to overcome its *prima facie* burden with respect to the rejections of the claimed invention under 35 U.S.C. §102 or alternatively under §103. At the outset, the Patent Office has merely relied on a single reference in support of the rejections. Contrary to the Patent office's position, the anticipation rejection is improper. Further, Appellants do not believe that one skilled in the art would be inclined to modify same to arrive at the claimed invention.

a. The Dialyzer Header Features of the Claimed Invention

Of the pending claims at issue, claims 1, 12 and 21 are the sole independent claims. Claim 1 relates to a dialyzer inlet header that includes a body designed to the attached to an end of a dialyzer; an inlet channel that provides fluid communication from an exterior of the dialyzer to an interior of the dialyzer wherein the inlet channel defines a fluid flow path that is axial to a fiber bundle located in the interior of the dialyzer. The dialyzer inlet header further includes at least one member for modifying the fluid flow path of fluid as it exits the inlet channel wherein the modifying member includes a curved vane that extends from a portion of the body.

Claims 3-11 depend from claim 1, either directly or indirectly. Claim 3 further recites that the dialyzer inlet header includes eight vanes. Claim 6 further recites that the member for modifying the fluid flow path defines a curved channel that extends into a portion of the body. Claim 7 depends from claim 6 and recites that the dialyzer inlet header includes eight channels. Claim 8 further recites that the member for modifying the fluid flow path obstructs the flow of fluid as it exits the fluid channel. Claim 9 depends from claim 8 and further recites that the member for modifying the fluid flow path further includes a disk located under an exit opening of the inlet fluid channel wherein the body can include a plurality of curved vanes (Claim 10) or can include a plurality of curved channels (claim 11).

Independent claim 12 relates to a dialyzer. The dialyzer includes a body; a fiber bundle located in an interior of the body; a blood inlet located at a first end of the body that includes a fluid flow channel that causes blood to flow in an axial direction with respect to the fiber bundle;

and a member located in juxtaposition and integral to the blood inlet that causes blood to flow to a perimeter region of a first end of the fiber bundle.

Claims 13-20 depend directly or indirectly from claim 12. Claim 13 further recites that the member is a curved vane that extends from a portion of the body. Claim 16 further recites that the member is a curved channel that extends into a portion of the body. Claim 17 recites that the member is a disk located under an exit opening of the inlet fluid channel wherein the member can include a plurality of curved vanes (Claim 18) or can include a plurality of curved channels (Claim 19).

Independent claim 21 relates to a dialyzer header. The dialyzer header includes a body member that has an inlet channel for providing fluid communication from an exterior to an interior of the header wherein the inlet channel defines a fluid path that is axial to a casing of a dialyzer to which the dialyzer head is attached. The body member of the dialyzer header includes a plurality of members that extend from the body member and that impart a circular motion to the fluid as it enters the interior of the header.

Claims 22-28 depend from claim 21 either directly or indirectly. Claim 22 further recites that the members include a plurality of curved vanes. Claim 23 further recites that the members include a plurality of curved channels. Claim 24 further recites that the members include a device that obstructs the flow of the fluid into portions of the interior of the header wherein the device is a disk located under the inlet channel (Claim 25), wherein the members can include eight vanes (Claim 27) or can include eight channels (Claim 28).

Appellants have discovered that the improved header design of the present invention can provide and improved blood flow into the interior of the dialyzer and specifically to the fiber bundle. This eliminates, or at least substantially reduces, the zones of low flow thereby reducing the potential for clotting while improving the ability to rinse the header of blood. See, Specification, page 2, lines 15-20. Appellants have demonstrated the desirable flow effects of the improved header design as disclosed in Appellants' specification on pages 19-25.

b. the Cited Reference Fails to anticipate or render obvious the improved header design of the Claimed Invention

Appellants believe that the Patent Office has improperly relied on the sole cited reference in support of the anticipation or the alternative obviousness rejection. Nowhere does the mere sole cited reference disclose or suggest the improved header design features as required by claims 1 and 3-28. Therefore, Appellants believe that the cited reference fails to anticipate and render obvious the claimed invention.

1. The Patent Office has improperly applied the anticipation and obviousness standards

At the outset, Appellants believe that the Patent Office has improperly applied the anticipation and obviousness standards in support of the rejection of claims 1 and 3-28. With respect to anticipation, clearly the intent of the Patent Office was to apply an obviousness standard and not anticipation. Indeed, the Patent Office opines that differences between the claimed invention and the cited reference are "merely a matter of obvious engineering choice" as provided in the Advisory Action dated October 22, 2003, a copy of which is attached hereto as Exhibit C. Thus, at a minimum, the anticipation rejection should be withdrawn and instead claims 1 and 3-28 should be rejected as allegedly obvious in view of the cited art.

Moreover, Appellants believe that the Patent Office has applied an improper legal standard in order to determine whether the claimed invention is obvious or not. In this regard, the Patent Office concludes that "the prior art element [allegedly] performs the function specified in the claim in substantially the same manner as the function is performed by the corresponding element described in the specification." See, Advisory Action, pages 2-3. Clearly, this is not the proper standard for obviousness. Instead, the Patent Office has relied on an infringement standard and even provides a plethora of case cites in support of same. Indeed, obviousness requires a different legal analysis as compared to infringement pursuant to the different statutory requirements for obviousness (e.g., 35 U.S.C. §103) and infringement (e.g., 35 U.S.C. §271). Thus, the alleged obviousness rejection of claims 1 and 3-28 should be reversed as a matter of law.

2. The cited reference fails to disclose or suggest the claimed invention

Despite the fact that the Patent Office has improperly applied both the anticipation and obviousness standards, Appellants believe that the cited art fails to disclose or suggest the claimed invention. Indeed, the sole cited reference is deficient with respect to a number of features of the improved header as claimed. Further, one skilled in the art would not be inclined to modify the cited art to remedy the deficiencies of same.

The dialyzer inlet header of claims 1 and 3-11 is novel and not obvious

Of claims 1, and 3-11, claim 1 is the sole independent claim. Claim 1 recites a dialyzer inlet header that includes, in part, at least one member for modifying the fluid flow path of a fluid as it exits the inlet channel wherein the member includes a curved vane extending from a portion of the body. In contrast, the cited reference merely discloses guide ribs (50) that are integral to an upper plate face of a guide plate (46). See, DE3435883, Abstract. Clearly, the guide plate (46) is a separate part as compared to the closure cap 24 as illustrated in Fig. 1 of the cited reference. Thus, the cited reference at least fails to disclose a curved vane that extends from a portion of the body of the dialyzer inlet header as required by claim 1.

Further, the cited reference fails to disclose additional features of the modifying member as further defined in the dependent claims. For example, claim 3 requires eight vanes that extend from a portion of the body as illustrated in Figure 2 of Appellants' specification. Claim 6 requires a curved channel that extends from the body that can include eight channels as further defined in claim 7 and illustrated in Figure 3 of Appellants' specification. Claims 8, 9, 10 or 11 further recite that the modifying member includes a disk and a number of curved vanes (claim 10) or curved channels (claim 11) as illustrated in Figure 4 of Appellants' specification.

Indeed, the cited reference requires the use of plate in combination with guide ribs in order to purportedly direct flow. Moreover, the guide ribs extend from the plate and not the closure cap where the plate is separately connected to the closure cap as previously discussed. Clearly, this contrasts the additional features as defined in dependent claims 3 and 6-11.

Nor, do Appellants believe that the sole cited reference suggests the improved flow features of the header as claimed. Again, the cited reference is deficient with respect to a

number of structural features as claimed and discussed above. As previously discussed, the improved header as claimed provides a modifying member that can impart a circular motion to fluid in contact with same as the fluid enters the interior of the header. In turn, this can effectively eliminate, or at least substantially reduce, the zones of low flow and thereby reduce the potential for clotting while improving the ability to rinse the header of blood.

In contrast, the DE 3435883 abstract merely states that "liq[uid] flows radially outwards in the upper section, through peripheral gaps or holes, and then radially inwards in the section below the plate." Clearly, this does not suggest a modifying member that can impart a circular motion as claimed. As previously discussed, Appellants have conducted a number of experiments to demonstrate the beneficial effects of the claimed invention. Thus, Appellants do not believe that one skilled in the art would be inclined to remedy the structural and functional deficiencies of the cited reference to arrive at the claimed invention.

The dialyzer of claims 12-20 is novel and not obvious

Of pending claims 12-20, claim 12 is the sole independent claim. Claim 12 recites a dialyzer that includes, in part, a member located in juxtaposition and integral to the blood inlet that causes blood to flow to a perimeter region of a first end of the fiber bundle. The member can include a curved vane (claim 13), a curved channel (claim 16), a disk with a number of curved vanes (claims 17 and 18) or a disk with a number of curved channels (claims 17 and 19) as illustrated in Figs 2-4 of Appellants' specification. As previously discussed, the member acts to impart a circular motion to fluid in contact with same, thus effectively eliminating, or at least substantially reducing, the zones of low flow. In this regard, the potential for clotting can be reduced while improving the ability to rinse the header of blood.

In contrast, the cited reference merely provides a plate that purportedly acts in combination with guide ribs to direct flow in a radial pattern as discussed above. The plate is separately connected to the closure cap where the guide ribs extend from the plate and not the closure cap. Clearly, this is deficient with respect to a member that can impart circular flow to alleviate zones of low flow through the dialyzer. Moreover, the claimed member is in juxtaposition and integral to the blood inlet, such as a curved vane or curved channel that can act

in combination with a disk as further defined in claims 13 and 16-19. Thus, Appellants believe that the cited reference is clearly distinguishable from claims 12-20.

The dialyzer header of claims 21-28 is novel and not obvious

Of pending claims 21-28, claim 21 is the sole independent claim. Claim 21 recites a dialyzer header that includes, in part, a body member that includes a number of members that extend therefrom and that impart a circular motion to the fluid as it enters the interior of the header. The members can include curved vanes or curved channels as further defined in claims 22 and 23 and illustrated in Figures 2 and 3 of Appellants' specification. Alternatively, the members include a disk in combination with eight vanes or eight channels that extend from the body member as further defined in claims 24-28 and illustrated in Figure 4 of Appellants' specification.

At the outset, the abstract of the cited reference merely provides a plate with guide ribs extending therefrom that purportedly act to direct flow in a radial pattern as discussed above. Clearly, this fails to disclose or suggest a number of members that extend from a body member of a dialyzer header to impart circular motion to a fluid that enters the interior of the header as required by claim 21. Again, this can effectively eliminate, or at least substantially reduce, the zones of low flow, and thus reduce the potential for clotting while improving the ability to rinse the header of blood.

Further, the guide ribs of the cited reference extend from the plate that is separately connected to the closure cap. This is clearly structurally different than the members that extend from the body of the header, let alone curved vanes or curved channels, such as eight curved vanes or curved channels as further defined by claims 22, 23, 27 and 28, respectively. Again, the improved structural features as claimed allow the dialyzer header to effectively impart a circular motion to the flow therethrough, thus effectively alleviating zones of low flow. Based on at least these structural and functional differences, Appellants believe that the sole cited reference fails to disclose or suggest the dialyzer header as required by claims 21-28.

Accordingly, Appellants respectfully request that the rejections under 35 U.S.C. § 102 and § 103 be reversed.

IX. CONCLUSION

Appellants' claimed invention set forth in claims 1 and 3-28 is neither taught nor suggested by the cited references, either alone or in combination. The Patent Office has failed to establish a *prima facie* case of anticipation and obviousness with respect to the rejection of the claimed invention. Accordingly, Appellants respectfully submit that the anticipation and obviousness rejections are erroneous in law and in fact and should therefore be reversed by this Board.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY _____

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Date: January 26, 2004

APPENDIX

1. A dialyzer inlet header comprising:

a body that is designed to be attached to an end of a dialyzer;

an inlet channel providing fluid communication from an exterior of the dialyzer to an interior of the dialyzer, the inlet channel defining a fluid flow path that is axial to a fiber bundle located in the interior of the dialyzer; and

at least one member for modifying the fluid flow path of a fluid as it exits the inlet channel, wherein the member includes a curved vane extending from a portion of the body.

3. The dialyzer inlet header of Claim 1 including eight vanes.

4. The dialyzer inlet header of Claim 1 wherein the inlet channel is located at a center of the body.

5. The dialyzer inlet header of Claim 1 wherein the header is sealed to an end of a dialyzer casing.

6. The dialyzer inlet header of Claim 1 wherein the member for modifying the fluid flow path defines a curved channel extending into a portion of the body.

7. The dialyzer inlet header of Claim 6 including eight channels extending into the body.

8. The dialyzer inlet header of Claim 1 wherein the member for modifying the fluid flow path obstructs the flow of fluid as it exits the fluid channel.

9. The dialyzer inlet header of Claim 8 wherein the member for modifying the fluid flow path further includes a disk located under an exit opening of the inlet fluid channel.

10. The dialyzer inlet header of Claim 9 wherein the body includes a plurality of curved vanes.

11. The dialyzer inlet header of Claim 9 wherein the body includes a plurality of curved channels.

12. A dialyzer comprising:

a body defining an interior and having a first end and a second end;

a fiber bundle located in the interior;

a blood inlet located at the first end and including a fluid flow channel that causes the blood to flow in an axial direction with respect to the fiber bundle; and

a member located in juxtaposition and integral to the blood inlet that causes blood to flow to a perimeter region of a first end of the fiber bundle.

13. The dialyzer of Claim 12 wherein the member is a curved vane extending from a portion of the body.

14. The dialyzer of Claim 12 wherein inlet channel is located at a center of the body.

15. The dialyzer of Claim 12 wherein the blood inlet is sealed to an end of the dialyzer body.

16. The dialyzer of Claim 12 wherein the member is a curved channel extending into a portion of the body.

17. The dialyzer of Claim 12 wherein the member is a disk located under an exit opening of the inlet fluid channel.

18. The dialyzer of Claim 17 wherein the member includes a plurality of curved vanes.

19. The dialyzer of Claim 17 wherein the member includes a plurality of curved channels.

20. The dialyzer of Claim 12 including a dialysate inlet and a dialysate outlet that define fluid flow channels that are radial to the fiber bundle.

21. A dialyzer header comprising a body member having an inlet channel providing fluid communication from an exterior to an interior of the header, the inlet channel defining a fluid path that is axial to a casing of a dialyzer to which the dialyzer head is attached and the body member including a plurality of members that extend from the body member and that impart a circular motion to the fluid as it enters the interior of the header.

22. The dialyzer header of Claim 21 wherein the members are a plurality of curved vanes.

23. The dialyzer header of Claim 20 wherein the members are a plurality of curved channels.

24. The dialyzer header of Claim 21 wherein the members include a device that obstructs the flow of the fluid into portions of the interior of the header.

25. The dialyzer header of Claim 24 wherein the device that obstructs is a disk located under the inlet channel.

26. The dialyzer inlet header of Claim 21 wherein inlet channel is located at a center of the body.

27. The dialyzer inlet header of Claim 21 including eight vanes.

28. The dialyzer inlet header of Claim 21 including eight channels extending into the body member.

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09/871,863	06/01/2001	Randolph H. Watkins	DI-5717	1448

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29200 7590 06/26/2003

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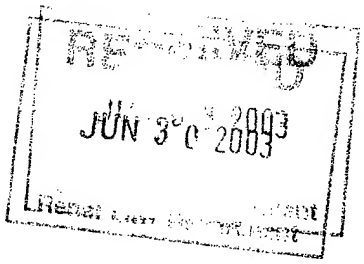

EXAMINER
MENON, KRISHNAN S

ART UNIT	PAPER NUMBER
1723	

DATE MAILED: 06/26/2003

DUE: 9-26-03

Please find below and/or attached an Office communication concerning this application or proceeding.

8/ 13

Office Action Summary	Application No. 09/871,863	Applicant(s) WATKINS ET AL.	
	Examiner Krishnan S Menon	Art Unit 1723	

-- Th MAILING DATE of this communication appears on th cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1 and 3-28 are pending.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3-28 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over DE 3435883 A1.

DE '883 teaches a dialyzer inlet header comprising a body (fig 1 and 2), inlet channel providing fluid communication (28) to the interior of the dialyzer and defining a flow path axial to the fiber bundle, one member modifying the fluid flow (fig 2) as it exits the inlet channel as in instant claim(s), and the member includes a curved vane extending from the body as in claim 1. The additional element in Independent claim 21: body member having plurality of members imparting a circular motion is item 50 of fig 2. Independent claim 12 is for a dialyzer having the following elements in addition to that of claim 1: body with first and second end (see figures: only one end shown), fiber bundle (20), blood inlet (28), and the member (fig 2) is integral and in juxtaposition to the blood inlet causing blood to flow to the perimeter.

Re the member including curved vanes being extending from or integral with the body: "...the use of a one piece construction instead of the structure disclosed in [the prior art] would be merely a matter of obvious engineering choice" (*In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965)).

DE '883 teaches additional elements of the dependent claims as follows: Curved vanes (50) and curved channels as in instant claim(s) 6, 10, 11, 13, 16, 18, 19, 22 and 23. Eight vanes and eight channels as in instant claim(s) 3,7, 27 and 28. Inlet channel is located at a center of the body (see fig 1) as in instant claim(s) 4, 14 and 26. Header (blood inlet) is sealed to an end of the dialyzer (see fig

1) as in instant claim(s) 5 and 15. Member includes a disk (46) that obstructs the flow as it exits into portions of the interior of the header as in instant claim(s) 8 and 24. The disc that obstructs the flow is located under the exit opening of the inlet channel as in instant claim(s) 9, 17 and 25. The dialyzate inlet and outlet fluid flow channels are radial to the fiber bundle as in instant claim(s) 20 (see fig 1, 2).

Response to Arguments

Applicant's arguments filed 3/9/03 have been fully considered but they are not persuasive.

Argument re improved header design giving improved flow: need to show supporting evidence that there is an unexpected substantial improvement over the prior art. Re "... the fluid flow path modifying member that extends from and/or is integral to a body..", see the rejection.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S Menon whose telephone number is 703-305-5999. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L Walker can be reached on 703-308-0457. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Krishnan Menon
Patent Examiner
June 17, 2003

Walker
W. L. WALKER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700

Records 1 of 1 In full Format

1. 1/19/1 DIALOG(R)File 351:Derwent WPI (c) 2002 Thomson Derwent. All rts. reserv.

004603859
WPI Acc No: 1986-107203/198617
XRAM Acc No: C86-045816
XRPX Acc No: N86-078889

Directing flow into hollow dialysis fibres by deflector - plate spanning widened end of housing

Patent Assignee: FRESENIUS AG (FREP)
Inventor: HEILMANN K; HOFFMANN R; KRAMP U
Number of Countries: 001 Number of Patents: 002
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week	
DE 3435883	A	19860417	DE 3435883	A	19840929	198617	B
DE 3435883	C	19880714				198828	

Priority Applications (No Type Date): DE 3435883 A 19840929
Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
DE 3435883	A		19		

Abstract (Basic): DE 3435883 C

The ends of a bundle of semi-permeable dialysis fibres (20) are embedded in known manner in a cast polymer layer (22). From a feed pipe (28) in a closure cap (24) liq. for dialysis enters the widened upper end (16) of the cylindrical housing (12). The space (38) between feed pipe mouth and fibre ends is divided into upper and lower sections by a transverse guide plate (46). Liq. flows radially outwards in the upper section, through peripheral gaps or holes, and then radially inwards in the section below the plate. The upper plate face has integral generally radial arcuate guide ribs (50). Gaps between lower plate and polymer layer is maintained by spacers.

USE/ADVANTAGE - For blood dialysis. Avoids dead zones for blood flow between feed pipe and fibres. (19pp Dwg.No.1/3)

Title Terms: DIRECT; FLOW; HOLLOW; DIALYSE; FIBRE; DEFLECT; PLATE; SPAN; WIDE; END; HOUSING
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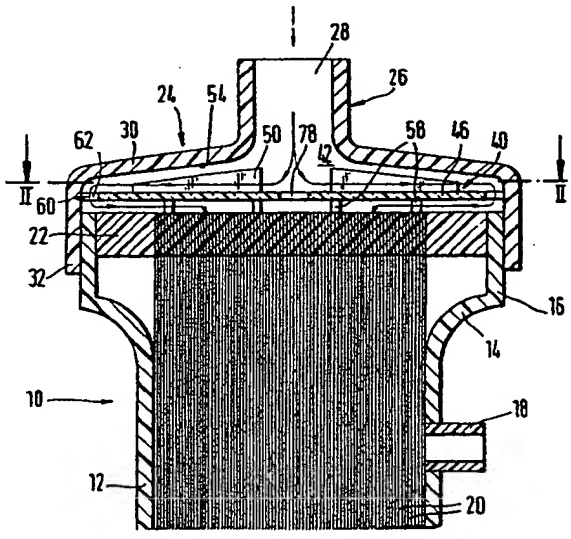
(54) Dialysator

Hohlfaserdialysator, der im Zwischenraum zwischen der Endkappe und der Vergußschicht der Hohlfasern eine Strömungsleiteinrichtung aufweist, die sich quer durch den gesamten Zwischenraum erstreckt und am Außenumfang zwischen Abstandshaltern einen ringförmigen Schlitz aufweist, durch den die zugeführte Flüssigkeit strömen kann. Demgemäß wird die Flüssigkeit durch die Strömungsleiteinrichtung zunächst radial nach außen gelenkt und fließt nach dem Durchfließen der Strömungsleiteinrichtung radial nach innen wieder zurück.



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Patentansprüche

1. Dialysator, aufweisend ein röhrenförmiges Gehäuse, das an seinen beiden Enden jeweils durch eine Vergußschicht verschlossen ist, eine Vielzahl von semipermeablen Hohlfasern, die sich durch das Gehäuse und die Vergußschicht hindurcherstrecken, auf die Enden des Gehäuses aufgesetzte Endkappen, die jeweils ein Zuführungsrohr aufweisen, wobei jeweils ein Zwischenraum zwischen der Vergußschicht und der Endkappe gebildet wird, der einerseits mit den Zuführungsrohren und andererseits mit dem Innenraum der Hohlfasern in Fluidverbindung steht, wenigstens einen aus dem Gehäuse austretenden Rohrstutzen und eine im Zwischenraum vorgesehene Strömungsleiteinrichtung, d a d u r c h g e k e n n z e i c h n e t , daß sich die Strömungsleiteinrichtung (40) quer über den Zwischenraum (38) unter Teilung des Zwischenraums in einen ersten und einen zweiten Durchströmraum (42, 44) erstreckt und mindestens im Bereich des Außenumfangs (68) der Strömungsleiteinrichtung (40) ein Strömungspfad (60) vorgesehen ist, der den ersten und zweiten Durchströmraum (42,44)

miteinander verbindet.

2. Dialysator nach Anspruch 1, dadurch gekennzeichnet, daß die Strömungsleiteinrichtung als Platte (46) ausgebildet ist, die entlang ihres Außenumfangs (68) eine Mehrzahl von Erhebungen (64) unter Bildung von Schlitzen (66) oder eine Mehrzahl von Bohrungen (70) aufweist.

3. Dialysator nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß die Strömungsleiteinrichtung (40) auf der der Vergußschicht (22) zugewandten Unterseite (56) Abstandshalterelemente (58) aufweist.

4. Dialysator nach einem der Ansprüche 1 - 4, dadurch gekennzeichnet, daß die Strömungsleiteinrichtung (40) auf der der Zuführungsöffnung (28) der Endkappe (24) zugewandten Oberfläche eine Mehrzahl von Strömungsleitelementen (50) aufweist.

5. Dialysator nach Anspruch 4, dadurch gekennzeichnet, daß die Strömungsleitelemente (50) eine derart radial nach außen gebogene Form aufweisen, daß sie der Flüssigkeit eine tangentiale Strömungskomponente verleihen.

6. Dialysator nach einem der Ansprüche 1 - 5, dadurch gekennzeichnet, daß die Innenoberfläche des zylinderförmigen Bereichs der Endkappe (24) eine Ringnut (74) aufweist, in die die Erhebungen (64) der Platte (46) eingerastet sind.

7. Dialysator nach einem der Ansprüche 1 - 6, dadurch gekennzeichnet, daß die Strömungsleiteinrichtung (40) eine Entlüftungseinrichtung aufweist.

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DIALYSATOR

Die Erfindung betrifft einen Dialysator, aufweisend ein röhrenförmiges Gehäuse, das an seinen beiden Enden jeweils durch eine Vergußschicht verschlossen ist, eine Vielzahl von semipermeablen Hohlfasern, die sich durch das Gehäuse und die Vergußschicht hindurcherstrecken, auf die Enden des Gehäuses aufgesetzte Endkappen, die jeweils ein Zuführungsrohr aufweisen, wobei jeweils ein Zwischenraum zwischen der Vergußschicht und der Endkappe gebildet wird, die einerseits mit den Zuführungsrohren und andererseits mit dem Innenraum der Hohlfasern in Fluidverbindung steht, wenigstens einem aus dem Gehäuse austretenden Rohrstutzen und eine im Zwischenraum vorgesehene Strömungsleiteinrichtung.

Aus der US-PS 32 28 877 ist ein derartiger Dialysator bekannt, bei dem beispielsweise Blut über den einen Zuführungsstutzen der einen Endkappe durch den Zwischenraum hindurch dem Hohlraum der Hohlfasern zugeführt und anschließend durch den zweiten Zwischenraum der zweiten Endkappe und durch den Abführungsstutzen hindurch abge-

führt wird. Durch die Poren der semipermeablen Membran erfolgt dann die Entfernung von harnpflichtigen Substanzen bzw. Wasser, sofern eine Dialysebehandlung durchgeführt wird. Andererseits kann jedoch aber auch dem röhrenförmigen Gehäuse über einen Zuführungsstutzen Dialysierflüssigkeit zugeführt werden, die die Außenoberfläche der Hohlfasern umströmt und anschließend aus einem weiteren Stutzen aus dem Rohr abgeschieden wird.

Wie bereits eingangs erwähnt, erstrecken sich die Hohlfasern durch das röhrenförmige Gehäuse und die an den Enden des Gehäuses befindlichen Vergußschichten hindurch, wobei regelmäßig die Hohlfasern nicht unmittelbar an den Gehäuserand geführt sind. So kann beispielsweise das Gehäuse im Randbereich aufgeweitet sein, wie dies beispielsweise aus der US-PS 4 001 110 ersichtlich ist, mit der Folge, daß ein ringförmig umlaufender Randbereich in der Vergußmasse gebildet wird, der nicht von den Hohlfasern durchsetzt ist. Dieser Randbereich steht auch nicht mit der Endkappe in Verbindung, die regelmäßig über das Gehäuse gestülpt ist und anschließend mit dem Gehäuse verbunden wird.

Dieser Randbereich führt insbesondere beim Einsatz als Hämodialysator zu Problemen, da das über den Zuführungsstutzen zugeführte Blut auch in diese Randbereiche strömt und aus diesen nicht abfließen kann, so daß es dort zu einer Gerinnung bzw. Verklumpung des Bluts kommt. Dies hat jedoch zur Folge, daß Hohlfasern während der Dialysebehandlung verstopft werden können und somit nicht mehr für die Dialysebehandlung zur Verfügung stehen.

Andererseits können jedoch aber auch in dem zweiten, stromab gelegenen Zwischenraum sich derartige Verklumpungen bilden, was bei dem Rücktransport des Bluts zum Körper des Patienten nicht unproblematisch ist.

Es wurden daher Versuche unternommen, diesen Randbereich möglichst zu beschränken bzw. zu beseitigen. So wurden beispielsweise Endkappen entwickelt, die eine zweite ringförmig umlaufende Wand aufweisen, die beim Aufsetzen der Endkappe auf das röhrenförmige Gehäuse in der unmittelbaren Nachbarschaft zu den äußeren Hohlfasern zu liegen kommt, so daß im wesentlichen der umlaufende, nicht von den Hohlfasern beaufschlagte Bereich der Vergußschicht beseitigt wird. Da jedoch bei einer derartigen Anordnung innerhalb der Kappe ein ringförmig mit Luft gefüllter Zwischenraum gebildet wird, muß dieser mit einer speziellen Dichtmasse vergossen werden, die über spezielle, in der Endkappe vorgesehene Stutzen zu- und abgeführt werden muß.

Eine derartige Herstellungsweise ist natürlich sehr zeitaufwendig und kostspielig, wobei zusätzlich nicht völlig sichergestellt werden kann, daß sämtliche Randbereiche der Vergußmasse, die nicht von den Hohlfasern durchzogen sind, völlig abgedeckt sind. Demgemäß können also auch bei dieser bekannten Ausführungsform sogen. Totzonen zurückbleiben, in denen auch nach dem Ausspülen mit steriler physiologischer Kochsalzlösung Blutreste zurückbleiben, was für den Benutzer bereits optisch höchst unerwünscht ist.

Zur Beseitigung dieser Probleme wurde bereits in der DE-OS 26 46 358 vorgeschlagen, das Blut über einen tangential zum Gehäuse bzw. zur Endkappe verlaufenden Anschlußstutzen anstelle des koaxial zur Gehäuselängsachse angeordneten Zuführungsstutzens zuzuführen, was bei dem in der DE-OS beschriebenen Dialysator mit zentralem Dialysateinlauf die Probleme mit den Totwasserzonen im wesentlichen beseitigte. Für den eingangs erwähnten Dialysator sind jedoch diese seitlich angeordneten Stutzen praktisch nicht einsetzbar, da sich wiederum Totzonen in dem Zwischenraum bilden.

In der DE-OS 26 46 358 ist in einer weiteren Ausführungsform eine kegelförmige Strömungsleiteinrichtung vorgeschlagen worden, die im wesentlichen den Zentralbereich der Vergußmasse abdeckt, der nicht von den Hohlfasern durchsetzt ist. Andererseits bleibt jedoch wiederum der vorstehend erwähnte ringförmige Außenrand übrig, so daß sich auch hier wiederum Totzonen bilden können.

Der Erfindung liegt daher die Aufgabe zugrunde, einen Dialysator der eingangs erwähnten Art so fortzubilden, daß die in den Randzonen des Zwischenraums zwischen der Vergußschicht und der Endkappe gebildeten Toträume beseitigt werden.

Die Lösung der Aufgabe erfolgt dadurch, daß sich die Strömungsleiteinrichtung quer über den Zwischenraum unter Teilung des Zwischenraums in einen ersten und einen zweiten Durchströmungsraum erstreckt und mindestens im Bereich des Außenumfangs der Strömungsleiteinrichtung ein Strömungspfad vorgesehen ist, der den ersten und zweiten Durchströmungsraum miteinander verbindet.

Mit dem erfindungsgemäßen Dialysator können die eingangs geschilderten Toträume wirksam beseitigt werden, da die Strömungsleiteinrichtung das zuströmende Fluid, insbesondere Blut, so führt, daß die Außenbereiche zwangsläufig durchströmt werden.

Erfindungsgemäß wird das durch den Zuführungsstutzen in den Zwischenraum eingeführte Blut zunächst mit der Strömungsleiteinrichtung in Kontakt gebracht, die dann das Blut im wesentlichen radial nach außen ablenkt, d.h. das Blut wird zunächst nahezu vollständig in den Außenbereich des Zwischenraums verdrängt.

In dem üblicherweise ringförmig umlaufenden Außenbereich des Zwischenraums, der die sonst üblichen, eingangs erwähnten, nicht mehr durchströmten Totbereiche aufweist, sind in der Strömungsleiteinrichtung Strömungspfade in Form von Durchbrechungen, Löchern, Schlitzen u.dgl. vorgesehen, durch die das Blut aus dem ersten Durchströmungsraum in den zweiten Durchströmungsraum abfließt. Die beiden Durchströmungsräume werden bekanntlich im Zwischenraum durch die Anordnung der Strömungsleiteinrichtung gebildet.

Nach dem Durchströmen dieses in der Strömungsleiteinrichtung vorgesehenen Strömungspfades fließt das Blut von außen, d.h. von der ringförmigen Wand der Abdeckkappe oder der Gehäusewand radial nach innen und gelangt dort in die Öffnungen der Hohlfasern, durch die es dann weiterfließt.

Somit wird das Fluid, insbesondere Blut, in dem erfindungsgemäßen Dialysator oder der Separationsvorrichtung mit Hilfe einer Strömungsleiteinrichtung im Zwischenraum zwischen der Abdeckkappe und der Vergußschicht zunächst nach außen gelenkt und kehrt nach dem Durchfließen der Strömungsleiteinrichtung von außen wieder nach innen zurück, mit der Folge, daß der gesamte Zwischenraum praktisch vollständig um- und durchflossen wird.

Als Strömungsleiteinrichtung wird vorteilhafterweise eine Platte verwendet, die in einer ersten Ausführungsform so bemessen ist, daß ihr Durchmesser geringer ist als der Innendurchmesser der Endkappe. Infolgedessen werden beim Einsetzen dieser Platte am Außenumfang Schlitze gebildet, durch die das Blut fließen kann. Des weiteren können vorteilhafterweise gemäß dieser Ausführungsform am Außenumfang Vorsprünge als Abstandshaltereinrichtungen vorgesehen sein, die so bemessen sind, daß sie die Anordnung der Platte in der Endkappe fixieren.

Vorteilhafterweise kann innerhalb der Endkappe eine ringförmige Nut umlaufen, in die die Vorsprünge einrasten, so daß dort vorteilhafterweise die Platte unverlierbar fixiert wird. Gemäß einer solchen Ausführungsform ist der Durchmesser der Platte einschließlich der Länge der Vorsprünge größer als der Innendurchmesser der Endkappe, so daß die Platte nur unter Einwirkung von Kraft in die Endkappe eingesetzt werden kann.

Andererseits ist jedoch aber auch eine Platte denkbar, die lose innerhalb der Endkappe angeordnet ist. In einem solchen Fall ist es vorteilhaft, daß neben den seitlichen Abstandshaltervorsprüngen noch axiale Abstandshaltereinrichtungen sowohl oberhalb als auch unterhalb der Plattenebene angeordnet sind, damit sicher ein erster als auch zweiter Durchströmungsraum gebildet werden. Ansonsten würde die Gefahr bestehen, daß einer dieser Räume durch die Platte dichtgepreßt wird und somit nicht mehr für die Durchströmung zur Verfügung steht.

Weiterhin kann die Strömungsleiteinrichtung vorteilhafterweise auf der dem Zuführungsstutzen zugewandten Oberfläche Strömungsteileinrichtungen aufweisen, die einerseits die zuströmende Flüssigkeit gleichmäßig in radialer Richtung verteilen und andererseits dem zugeführten Flüssigkeitsstrom eine bestimmte Strömungsrichtung aufprägen können. So können diese Strömungsteileinrichtungen der zuströmenden Flüssigkeit infolge ihrer Form eine tangentiale Strömungskomponente aufprägen, wodurch der Aufprall der Flüssigkeit auf die Außenwand gemildert werden kann. In einem derartigen Fall können die Strömungsteileinrichtungen natürlich auch als Abstandshalter für den ersten Durchströmungsraum dienen.

Des weiteren kann zur Verbesserung der Entlüftung des zweiten Durchströmungsraums, d.h. des Raums, bei dem die Flüssigkeit radial von außen nach innen strömt, im Bereich des Zentrums wenigstens eine Öffnung vorgesehen

sein, durch die die Entlüftung in den ersten Durchströmungsraum sichergestellt wird. Da die Flüssigkeit oder das Blut zu Beginn der Einströmphase möglichst gleichmäßig von allen Seiten nach innen strömen soll, kann die Bildung von Luftblasen u.dgl. zu befürchten sein, die stationär im zweiten Durchströmungsraum verbleiben und die einen Teil der Öffnungen der Hohlfasern somit blockieren. Dies wird durch wenigstens eine Öffnung im Zentralbereich der Strömungsleiteinrichtung beseitigt.

Weiterhin ist an sich die Form der Platte unkritisch. Sie kann eben oder aber mit einer erhabenen Struktur ausgebildet sein, wobei die erhabene Struktur die Strömung begünstigen kann. So kann beispielsweise eine Platte mit Kegelstruktur vorteilhafterweise für die erfindungsgemäßen Zwecke eingesetzt werden.

Weitere Einzelheiten, Merkmale und Vorteile der Erfindung sind anhand der nachfolgenden Beschreibung von Ausführungsbeispielen unter Bezugnahme auf die Zeichnung erläutert. Es zeigen:

Fig. 1 einen Teilschnitt durch eine erste Ausführungsform eines erfindungsgemäßen Dialysators gemäß Linie I-I in Fig. 2,

Fig. 2 einen Schnitt durch den Dialysator nach Fig. 1 gemäß Linie II-II in Fig. 1,

Fig. 3 eine vergrößerte Schnittdarstellung durch eine Hälfte der symmetrischen Endkappe einer anderen Ausführungsform eines erfindungsgemäßen Dialysators in einer Fig. 1 entsprechenden Darstellung.

In Fig. 1 ist der Dialysator mit 10 ersichtlich, der aus einem Gehäuse 12 besteht, das sich gemäß der in Fig. 1 gezeigten Ausführungsform in seinem Endbereich 14 aufweitet und wieder in einen zylinderförmigen Abschlußbereich 16 übergeht. Diese Aufweitung ist jedoch nicht

erfindungswesentlich. Dementsprechend kann auch das Gehäuse 12 als glatter Hohlzylinder ausgebildet sein.

In der Nähe des Endbereichs 14 ist im Gehäuse 12 ein rohrförmiger Stutzen 18 vorgesehen, der mit einer Schlauchleitung verbunden werden kann. Üblicherweise sind bei einem derartigen Dialysator 10 zwei Stutzen 18 vorgesehen, die vorteilhafterweise diagonal zueinander angeordnet sind.

In dem Gehäuse 12 ist eine Vielzahl von mikroporösen, semipermeablen Hohlfasern 20 vorgesehen, wie sie üblicherweise bei einem Hohlfaserdialysator zum Einsatz kommen. Auch diese Hohlfasern sind längst bekannt und somit nicht Gegenstand der Erfindung.

Diese Hohlfasern liegen in dem Gehäuse 12 in Form eines dichtgepackten Bündels vor, das gegebenenfalls verwebt sein kann.

Um den Innenraum des Gehäuses 12, das einen ersten von einer ersten Flüssigkeit durchströmten Raum darstellt, von dem Innenraum der Hohlfasern 20 zu trennen, der einen zweiten von einer Flüssigkeit, vorteilhafterweise Blut, durchströmten Raum darstellt, zu trennen, ist der Abschlußbereich 16 des Gehäuses 12 mit einer Vergußschicht 22 aus einem Polymerisat versehen, die von den Hohlfasern 20 durchsetzt ist, wobei die Öffnungen der Hohlfasern 20 nicht mit der Vergußschicht 22 verschlossen sind, also von der Außenoberfläche der Vergußschicht her offen sind.

Eine derartige Anordnung wird dadurch hergestellt, daß man das offene rohrförmige Gehäuse 12 zunächst mit einem Bündel von Hohlfasern 20 versieht, anschließend in den Abschlußbereich des Gehäuses eine flüssige Vergußmasse einführt, diese aushärten läßt und zum Schluß die Außen-

oberfläche der Vergußschicht 22 derart bearbeitet, daß sie einerseits plan ist und andererseits sämtliche Hohlfasern nach außen hin offen sind.

Auf ein derart mit den Hohlfasern 20 bestücktes Gehäuse 12 wird abschließend die in Fig. 3 näher gezeigte Endkappe 24 aufgesetzt, die anschließend mit dem Abschlußbereich 16 des Gehäuses 12 auf übliche Weise sterildicht verschweißt oder verklebt wird.

Diese Endkappe 24 weist einen Zuführungsstutzen 26 mit einer Zuführungsöffnung 28 auf, wobei die Achse des Zuführungsstutzens 26 koaxial zur Längsachse des Gehäuses 12 angeordnet ist.

Von diesem Zuführungsstutzen 26 erstreckt sich die Endkappe 24 über den Kappenbereich 30 nach außen und geht in einen hohlzylinderförmigen Endbereich 32 über, der größtenteils über den Abschlußbereich 16 des Gehäuses 12 geschoben ist, wie dies aus Fig. 3 ersichtlich ist. Mit diesem Endbereich 32 ist die Kappe 24 über die Schweißschicht 34 verbunden.

Wenn die Endkappe 24 auf das Gehäuse 12 aufgesetzt ist, wird zwischen der Oberfläche 36 der Vergußschicht 22 und der Innenoberfläche der aufgesetzten Endkappe 24 ein Zwischenraum 38 gebildet, der durch eine Strömungsleiteinrichtung 40 in einen ersten Durchströmraum 42 und einen zweiten Durchströmraum 44 unterteilt wird.

Die Strömungsleiteinrichtung 40 ist vorteilhafterweise als Platte 46 ausgebildet, deren Durchmesser im wesentlichen dem Innendurchmesser der Endkappe 24 entspricht und die üblicherweise kreisförmig ausgeführt ist. Diese Platte 46 erstreckt sich vorteilhafterweise quer über die der Vergußschicht 22 zugewandte Öffnung der Endkappe 24 und deckt diese im wesentlichen ab.

Wie in Fig. 1 oder 3 gezeigt, ist die Platte 46 im wesentlichen eben. Andererseits kann sie jedoch auch kegelförmig ausgestaltet sein, wobei die Spitze des Kegels vorteilhafterweise zur Zuführungsöffnung 28 ausgerichtet ist.

Vorteilhafterweise sind auf der der Zuführungsöffnung 28 zugewandten Oberfläche 48 der Platte 46 Strömungsleitelemente 50 in Form von Leitschaufeln angeordnet, wie dies aus Fig. 2 ersichtlich ist.

Diese Strömungsleitelemente 50 erstrecken sich in radial gekrümmter Weise, beginnend in der Nachbarschaft des Mittelpunkts der Platte 46, nach außen und enden im Bereich des Randes 52 der Platte 46. Diese Strömungsleitelemente 50 können eine gerade oder - wie in Fig. 2 gezeigt - eine gekrümmte Form aufweisen, wobei die zuletzt genannte Form bevorzugt ist, da sie der zuströmenden Flüssigkeit eine tangentiale Strömungskomponente aufprägen können.

Weiterhin können die Strömungsleitelemente 50 als Abstandshalter zur Innenoberfläche 54 der Endkappe 24 dienen und somit verhindern, daß sich die Platte 54 an der Endkappe 24 anlegt.

Weiterhin weist die Unterseite 56 der Platte 46, die der Vergußschicht 22 zugewandt ist, ebenfalls Abstandshalterelemente 58 auf, die verhindern, daß eine lose eingelegte Platte 46 beim Anströmen durch Flüssigkeit aus der Zuführungsöffnung 28 die Cberfläche 36 der Vergußschicht 22 und damit die Öffnungen der Hohlfasern 20 zusetzt. Diese Abstandshalterelemente 58 sind in Form von punktartigen Erhebungen auf der Unterseite 56 der Platte 46 angeordnet und sind aus Fig. 2 dadurch ersichtlich, da die Platte 46 vorteilhafterweise aus einem transparenten Kunststoffmaterial, wie Polycarbonat, besteht.

Zur Herstellung einer Fluidverbindung zwischen dem ersten Durchströmraum und dem zweiten Durchströmraum 44, also einer Fluidverbindung zwischen der Zuführungsöffnung 28 und den Öffnungen der Hohlfasern 20 durch den Zwischenraum 38, ist am Außenumfang der Strömungsleiteinrichtung 40 ein Strömungspfad 60 vorgesehen, der die beiden Durchströmungsräume 40 und 42 miteinander verbindet. Somit weist die Platte 46 im Einbauzustand an ihrem Außenumfang eine Mehrzahl von Durchbrechungen 62 auf, die - wie aus Fig. 2 und 3 ersichtlich ist - dadurch gebildet werden, daß am Außenumfang der Platte 46 regelmäßig um den Außenumfang verteilt, mehrere radial nach außen vorstehende Erhebungen oder Noppen 64 vorgesehen sind. Die Platte 46 mit den Erhebungen 48 ist dabei so bemessen, daß sie innerhalb der Endkappe 24 im wesentlichen ohne Spiel angeordnet werden kann, d.h. die Erhebungen 64 berühren nahezu die Innenoberfläche des zylindrischen Bereichs der Endkappe 24.

Demzufolge wird der Strömungspfad 60 dadurch gebildet, daß - wie in Fig. 2 strichliert ausschnittsweise gezeigt - ein ringförmiger Schlitz 66 zwischen dem Außenumfang der Platte 46 und der Innenoberfläche des Endbereichs 32 der Endkappe 24 gebildet wird. Dabei entspricht die Schlitzbreite der Höhe der Erhebungen 64, die um den Außenumfang 68 der Platte 46 verteilt sind.

Andererseits kann anstelle dieser Erhebungen 64 der Außenumfang 68 der Platte 46 unmittelbar mit der Innenoberfläche des Endbereichs 32 der Endkappe 24 verbunden sein. Gemäß dieser Ausführungsform, die jedoch weniger bevorzugt ist, sind im Randbereich 68 der Platte 46, wie dies in Fig. 2 strichliert gezeigt ist, Bohrungen 70 vorgesehen, die gleichmäßig um den Randbereich 68 verteilt sind. Wesentlich an dieser Ausführungsform ist lediglich, daß die freie Randzone 72, die durch den Endbereich des Gehäuses 12 und den Endbereich der Vergußschicht 22 gebildet ist, wirksam von der Flüssigkeit an- bzw. durchströmit wird.

Gemäß einer weiteren bevorzugten Ausführungsform ist die Endkappe 26 im Bereich des Zwischenraums 38 auf ihrer Innenoberfläche mit einer umlaufenden Ringnut 74 versehen, an die sich in Richtung auf die der Vergußschicht 22 zugewandte Öffnung der Endkappe 24 eine Einlaufschräge 76 auf der Innenoberfläche des Endbereichs 72 der Endkappe 24 anschließt. Diese Einlaufschräge 76 verengt sich dabei in Richtung auf die Ringnut 74. Hierdurch wird das Einsetzen der Platte 46, die am Außenumfang die Erhebungen 64 aufweist, erleichtert.

Gemäß einer bevorzugten Ausführungsform läßt sich diese Platte paßgenau in die Ringnut 74 unverlierbar einsetzen, wobei die Tiefe der Ringnut nur einen Bruchteil der Höhe der Erhebungen 64 beträgt.

Bei einer derart fixierten Anordnung können natürlich die Abstandshalterelemente 50 bzw. 58 oberhalb und unterhalb der Platte 46 entfallen.

Weiterhin weist die Strömungsleiteinrichtung 40 im Bereich des Zentrums wenigstens eine Entlüftungseinrichtung in Form wenigstens einer Bohrung 78 auf, die derart ausgestaltet ist, daß sie nur einen Bruchteil der zufließenden Flüssigkeit durchläßt, so daß der weit überwiegende Teil über den Strömungspfad 60, der den ersten Durchströmraum mit dem zweiten Durchströmraum miteinander verbindet, abfließt.

Der in Fig. 1 - 3 gezeigte Dialysator wird auf folgende Weise betrieben:

Nachdem der Zuführungsstutzen 26 mit der Blutleitung in Verbindung gebracht worden ist, wird Blut der Zuführungsöffnung 28 zugeführt und gelangt anschließend mit der Strömungsleiteinrichtung 40, insbesondere mit der Platte 46 in Kontakt. Diese Platte 46 leitet vorteilhafterweise mittels der Strömungsleitelemente 50 das Blut nach außen, wie

dies in Fig. 1 durch die pfeilförmig gezeigte Strömungsführung dargestellt ist. Am Außenumfang 68 der Platte 46 gelangt das Blut durch die Durchbrechungen 62 bzw. den ringförmig umlaufenden Schlitz 66 von dem ersten Durchströmraum 42 in den zweiten Durchströmraum 44 und strömt dort radial nach innen, bis es zu den Öffnungen der Hohlfasern 20 gelangt, durch die es anschließend auf die übliche Weise weiterströmt.

Demgemäß wird also das Blut nach der zentralen Zuführung radial nach außen gedrängt und fließt anschließend von außen wieder radial zurück. Dabei kann im zweiten Durchströmraum 44 ein Luftpolster eingeschlossen werden, das durch die in der Platte 46 vorgesehene Bohrung 78 vorteilhafterweise verdrängt werden kann.

Der Dialysator 10 wird vor und nach der Behandlung vorteilhafterweise mit physiologischer Kochsalzlösung gespült, d.h. das Blut wird nach Beendigung der Dialyse wieder vollständig in den Körper des Patienten zurückgeführt. Mit der erfindungsgemäßen Vorrichtung kann der Dialysator 10 vollständig von Blut freigespült werden, da die Totzonen, die bei dem bekannten Dialysator nicht zu reinigen waren, durch die erfindungsgemäße Strömungsleiteinrichtung 40 vollständig durchflossen werden, mit der Folge, daß sich bei der Dialyse kein Blut absetzt und nach Beendigung der Dialyse sämtliche Blutreste aus dem Dialysator 10 entfernt werden können. Des weiteren muß weniger Spüllösung bei dem erfindungsgemäßen Dialysator 10 eingesetzt werden als bei dem bekannten Dialysator, da die Freispülung wesentlich leichter erfolgt.

Weiterhin hat der erfindungsgemäße Dialysator den Vorteil, daß er im wesentlichen handlingsunabhängig ist und auch im wesentlichen keine Pumpstöße durch pulsierende Blutpumpen stören. Insofern läßt sich dieser Dialysator

auch bei niedrigen Strömungsgeschwindigkeiten ohne zusätzliches Abklemmen der flexiblen Zuführungsschläuche, was zur Erhöhung der Blutflußgeschwindigkeit üblicherweise in der Klinik angewandt wird, einsetzen.

- Leerseite -

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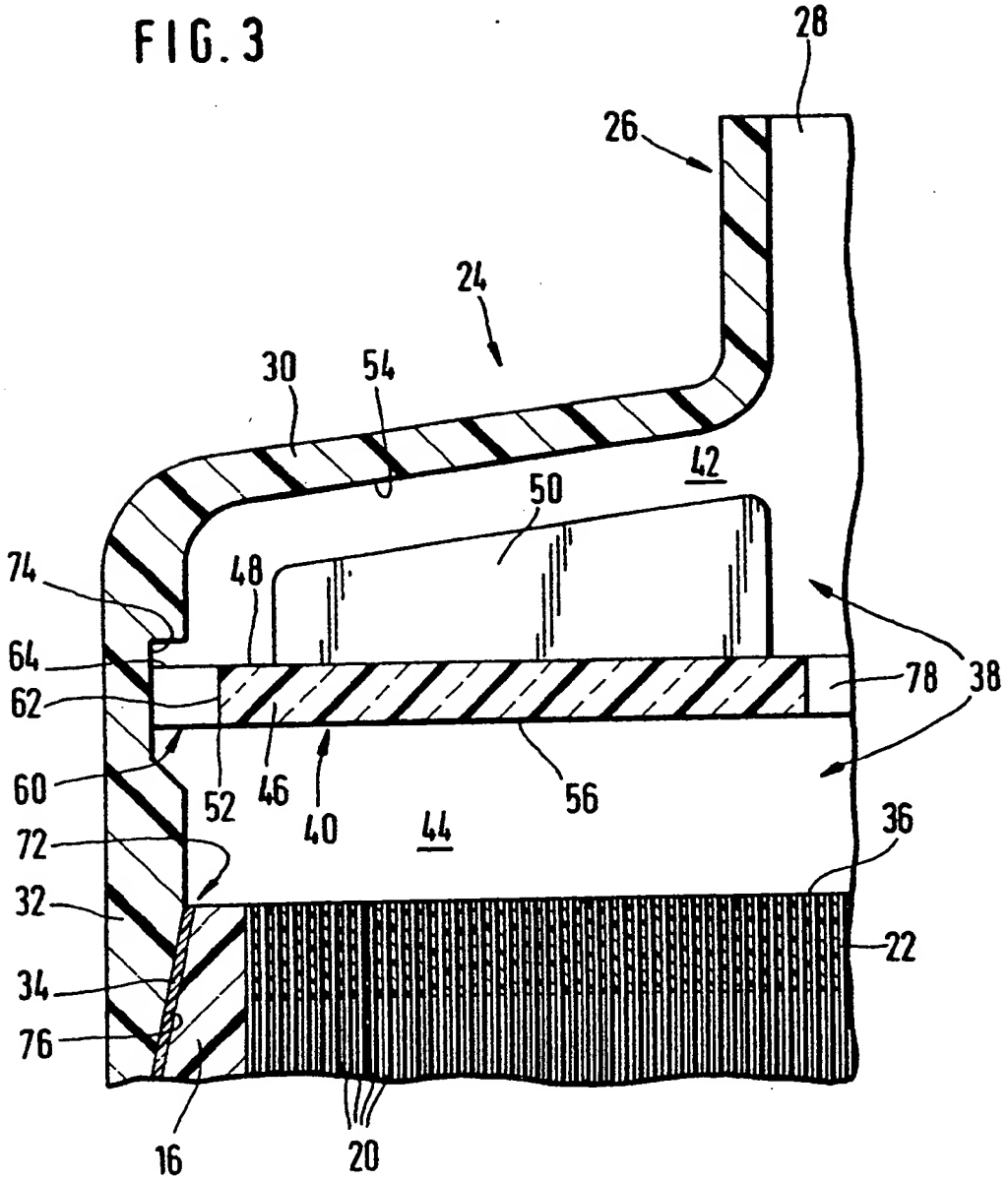
FIG. 3



Nummer: 34 35 883
Int. Cl.⁴: A 61 M 1/18
Anmeldetag: 29. September 1984
Offenlegungstag: 17. April 1986

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FIG. 1

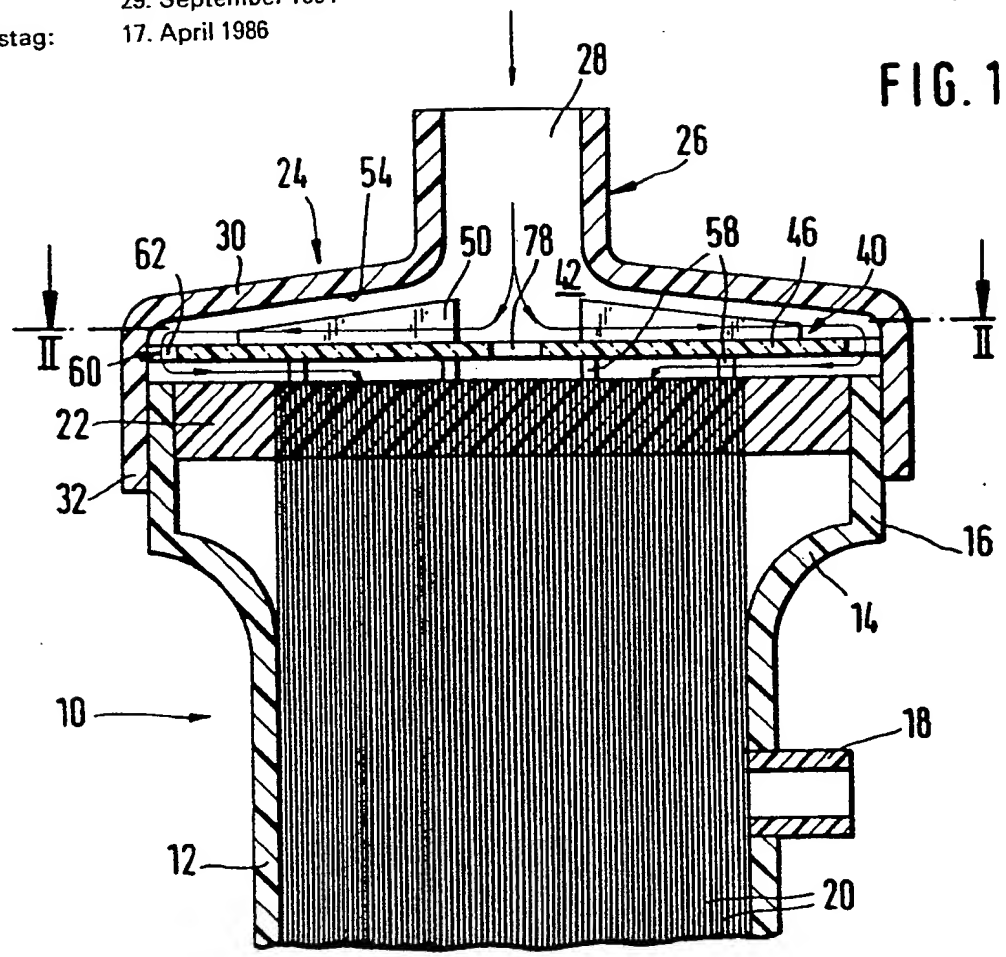


FIG. 2

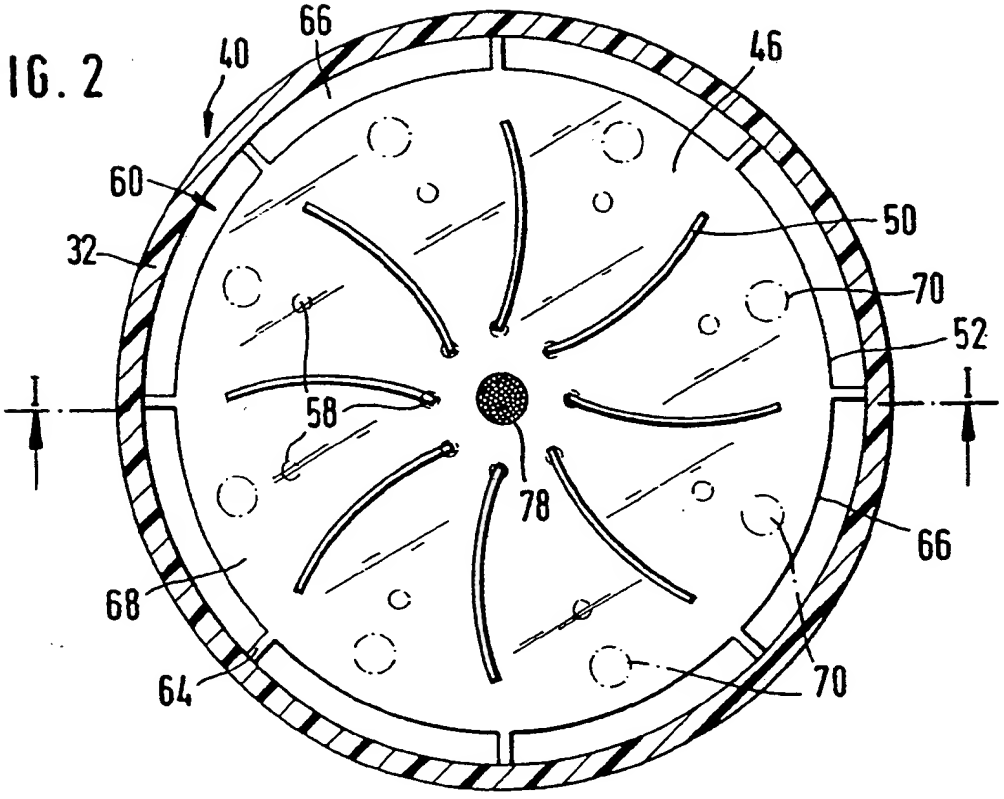


FIG.1

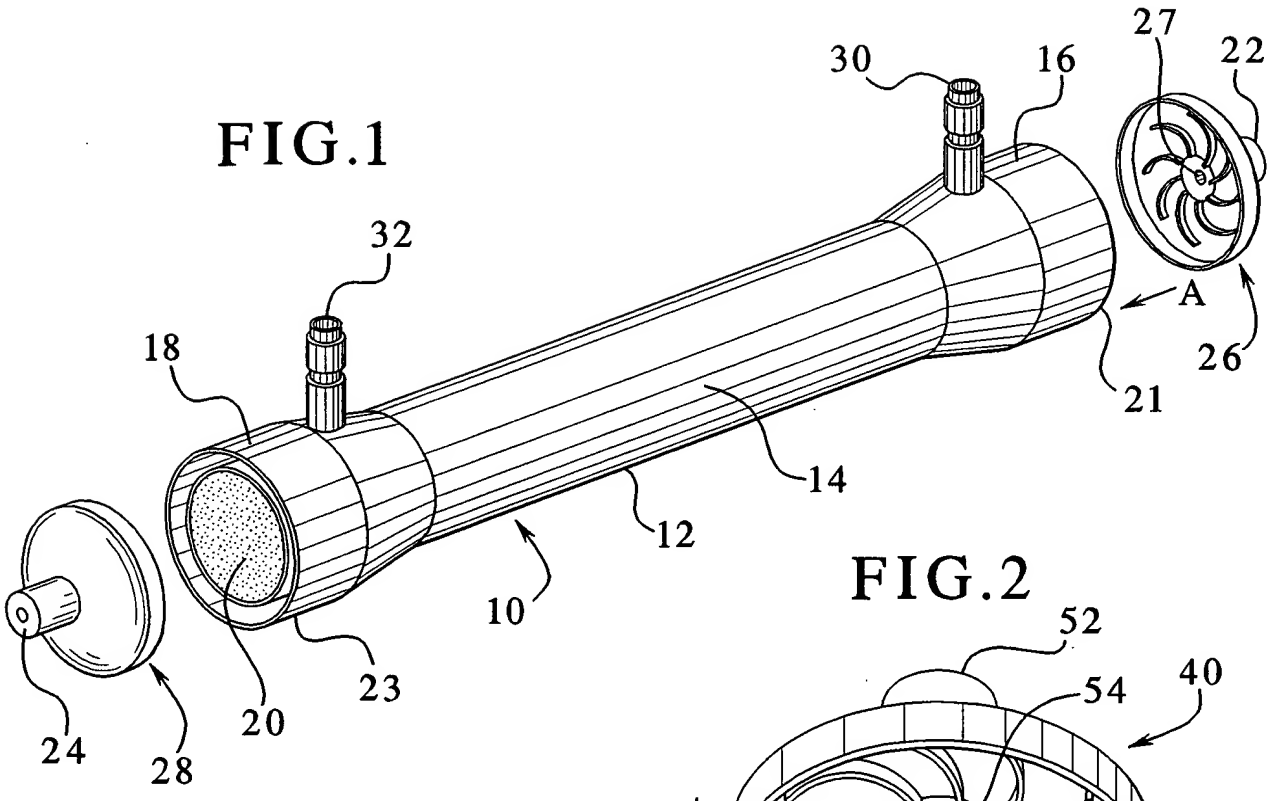


FIG.2

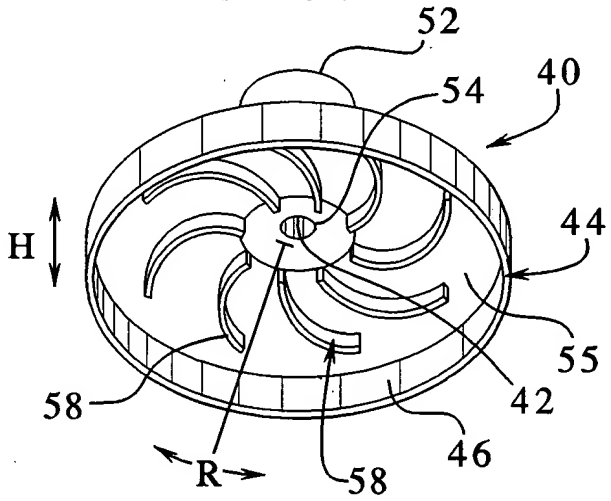


FIG.3

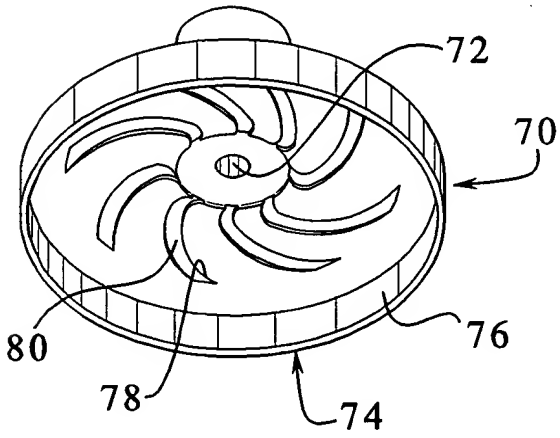
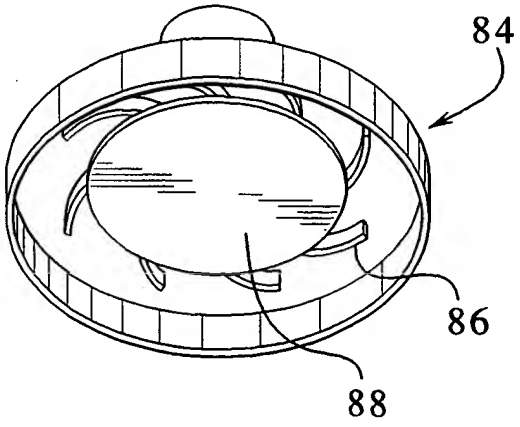


FIG.4



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/871,863	06/01/2001	Randolph H. Watkins	DI-5717	1448

29200 7590 10/22/2003

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EXAMINER	
MENON, KRISHNAN S	

ART UNIT	PAPER NUMBER
1723	

DATE MAILED: 10/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

CASE 5717
DKT. DATE ____ SEEN BY ATTY. ____
FINAL DATE 12-29-03 RESP. SENT ____
SUBJECT Advisory Action

PTO-90C (Rev. 10/03)

10.03

Advisory Action	Application No. 09/871,863	Applicant( ) WATKINS ET AL.	
	Examiner Krishnan S Menon	Art Unit 1723	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 29 September 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ they raise the issue of new matter (see Note below);
   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: _____.
3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attached Response to Arguments*.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1 and 3-28*.

   Claim(s) withdrawn from consideration: _____.
8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Response to Arguments

Applicant's arguments filed 9/29/03 have been fully considered but they are not persuasive. Argument re 35 USC 102/103 rejection: When the interpretation of the claim(s) is or may be in dispute, i.e., given one interpretation, a rejection under 35 U.S.C. 102 is appropriate and given another interpretation, a rejection under 35 U.S.C. 103(a) is appropriate. See MPEP § § 2111-2116.01 for guidelines on claim interpretation.

Argument re " ... the member including curved vanes being extending from or integral with the body ..." See the case law: *In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965): "...the use of a one piece construction instead of the structure disclosed in [the prior art] would be merely a matter of obvious engineering choice".

Argument re structural difference of the dialyzer header between the claimed invention and the prior art DE 343 5883: In this case, the prior art element:

(A) performs the identical function specified in the claim in substantially the same way, and produces substantially the same results as the corresponding element disclosed in the specification. Kemco Sales, Inc. v. Control Papers Co., 208 F.3d 1352, 54 USPQ2d 1308 (Fed. Cir. 2000)

(B) is not excluded by any explicit definition provided in the specification for an equivalent. A person of ordinary skill in the art would have recognized the interchangeability of the element shown in the prior art for the corresponding element disclosed in the specification. Caterpillar Inc. v. Deere & Co., 224 F.3d 1374, 56 USPQ2d 1305 (Fed. Cir. 2000); Al-Site Corp. v. VSI Int'l, Inc., 174 F.3d 1308, 1316, 50 USPQ2d 1161, 1165 (Fed. Cir. 1999); Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus. Inc., 145 F.3d 1303, 1309, 46 USPQ2d 1752, 1757 (Fed. Cir. 1998); Lockheed

Aircraft Corp. v. United States , 193 USPQ 449, 461 (Ct. Cl. 1977); Data Line Corp. v. Micro Technologies, Inc., 813 F.2d 1196, 1 USPQ2d 2052 (Fed. Cir. 1987).

(C) is an equivalent of the claimed element. There are insubstantial differences between the prior art element and the corresponding element disclosed in the specification. IMS Technology, Inc. v. Haas Automation, Inc., 206 F.3d 1422, 1436, 54 USPQ2d 1129, 1138 (Fed. Cir. 2000); Warner-Jenkinson Co. v. Hilton Davis Chemical Co., 117 S. Ct. 1040, 41 USPQ2d 1865, 1875 (1997); Valmont Industries, Inc. v. Reinke Mfg. Co., 983 F.2d 1039, 25 USPQ2d 1451 (Fed. Cir. 1993). See also Caterpillar Inc. v. Deere & Co., 224 F.3d 1374, 56 USPQ2d 1305 (Fed. Cir. 2000) the prior art element is a structural equivalent of the corresponding element disclosed in the specification. In re Bond, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990). That is, the prior art element performs the function specified in the claim in substantially the same manner as the function is performed by the corresponding element described in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S Menon whose telephone number is 703-305-5999. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L Walker can be reached on 703-308-0457. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Krishnan Menon
Patent Examiner

JOSEPH DROUGE
PRIMARY EXAMINER